UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 30, 2018

STRATA
SKIN SCIENCES

STRATA SKIN SCIENCES, INC.
(Exact Name of Registrant Specified in Charter)

Delaware	**000-51481**	**13-3986004**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

100 Lakeside Drive, Suite 100, Horsham, Pennsylvania	**19044**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **215-619-3200**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

On August 30, 2018 Strata Skin Sciences, Inc. (the "Company") and a member of the Company's board of directors, Uri Geiger, in his individual capacity (and together with the Company, the "plaintiffs"), filed a complaint seeking an Action for a Declaratory Judgment in the Court of Common Pleas, Montgomery County, Pennsylvania, against Ra Medical Systems, Inc., a Delaware Corporation with a principal place of business at 2070 Las Palmas Drive, Carlsbad, CA 92011.

In the action, the plaintiffs are seeking a declaration that the plaintiffs are not liable to the defendant, Ra Medical Systems, for any reason, including but not limited to claims of tortious interference, defamation, libel, or unfair competition and did not tortuously interfere with defendant, Ra Medical Systems', initial public offering or engage in any other wrongdoing as a result of statements made by Mr. Geiger, about which defendant, Ra Medical Systems, has threatened to sue the Company. The declaratory judgment action also seeks a declaration that neither plaintiff has made an actionable statement to UBS Investment Bank regarding defendant, Ra Medical Systems', potential initial public offering.

A copy of the Action for Declaratory Judgment is submitted herewith as Exhibit 99.1`

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

Item 9.01 Financial Statements and Exhibits

Exhibits.

Exhibit Number	**Description**
99.1	Action For Declaratory Judgment

Exhibit Index	Description
99.1	Action For Declaratory Judgment

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STRATA SKIN SCIENCES, INC.

Date: August 30, 2018

By: /s/ Matthew C. Hill
Matthew C. Hill
Chief Financial Officer

EXHIBIT 99.1

STRATA SKIN SCIENCES, INC. and URI GEIGER, Plaintiffs, v. RA MEDICAL SYSTEMS, INC., Defendant.	IN THE COURT OF COMMON PLEAS MONTGOMERY COUNTY, PENNSYLVANIA CIVIL ACTION NO. 18-

NOTICE TO PLEAD

To: Defendant Ra Medical Systems, Inc.
2070 Las Palmas Drive
Carlsbad, CA 92011

You are hereby notified to file a written response to the enclosed Complaint within twenty (20) days from service hereof or a judgment may be entered against you.

Dated: August 30, 2018 STEVENS & LEE, P.C.

By: */s/ Joseph Wolfson*
Joseph Wolfson
Attorney Id. No. 44431
Neil C. Schur
Attorney Id. No. 79068
1818 Market Street, 29th Floor
Philadelphia, PA 19103
Ph: (215) 751-1249/1944
Fax: (610) 988-0808
Email: jwo@stevenslee.com
ncsc@stevenslee.com

Attorneys for Plaintiffs Strata Skin Sciences, Inc. and Uri Geiger

STEVENS & LEE, P.C.
Joseph Wolfson
Attorney Id. No. 44431
Neil C. Schur
Attorney Id. No. 79068
1818 Market Street, 29th Floor
Philadelphia, PA 19103
Ph: (215) 751-1249/1944
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Attorneys for Plaintiffs Strata Skin Sciences, Inc. and Uri Geiger

STRATA SKIN SCIENCES, INC. and URI GEIGER, Plaintiffs, v. RA MEDICAL SYSTEMS, INC., Defendant.	IN THE COURT OF COMMON PLEAS MONTGOMERY COUNTY, PENNSYLVANIA CIVIL ACTION NO. 18-

ACTION FOR DECLARATORY JUDGMENT

Plaintiffs Strata Skin Sciences, Inc. ("**Strata**") and Uri Geiger ("**Geiger**") (collectively, where appropriate, "**Plaintiffs**") file this Action for Declaratory Judgment against defendant Ra Medical Systems, Inc. ("**Ra**") pursuant to Rule 1601 of the Pennsylvania Rules of Civil Procedure and Pennsylvania's Declaratory Judgments Act, 42 Pa. C.S.A. §§ 7531 *et seq.*

Plaintiffs seek a declaration that: (1) Plaintiffs are not liable to defendant for any reason, including but not limited to claims of tortious interference, defamation, libel, or unfair competition and did not otherwise tortiously interfere with Ra's initial public offering, or engage in any other wrongdoing, as a result of statements made in Mr. Geiger's May 22, 2018 email about which Ra has threatened to initiate litigation against Strata; (2) Plaintiffs made no

actionable statements to UBS Investment Bank ("**UBS**") regarding Ra; (3) Strata is not a successor or assign of PhotoMedex, Inc. ("**PhotoMedex**"), and therefore, Ra cannot enforce its Settlement Agreement with PhotoMedex against Strata; (4) any dispute regarding Mr. Geiger's May 22, 2018 email does not arise out of or relate to facts, events, occurrences or omissions up to and including the date of the Settlement Agreement, and therefore such a dispute was not released pursuant to the Settlement Agreement; and (5) any dispute regarding Mr. Geiger's May 22, 2018 email is not an "action, suit or proceeding with respect to" the Settlement Agreement.

Parties

1. Strata is a Delaware corporation with a principal place of business at 100 Lakeside Drive, #100, Horsham, PA 19044. The common shares of Strata are publicly traded on the Nasdaq exchange under the symbol "SSKN."

2. Mr. Geiger is an adult individual residing in Cresskill, New Jersey. Mr. Geiger was at all times relevant hereto Managing Partner of Accelmed Growth Partners, L.P. ("**Accelmed**") and, as of May 29, 2018, Chair of the Board of Directors of Strata.

3. Ra is a Delaware corporation with a principal place of business at 2070 Las Palmas Drive, Carlsbad, CA 92011. Ra is a privately held company that filed papers in late July 2018 with the United States Securities and Exchange Commission ("**SEC**") to raise approximately $86 million in an initial public offering, to be publicly traded under the symbol "RMED."

Jurisdiction and Venue

4. This Court has jurisdiction over this action because, pursuant to 42 Pa. C.S.A. § 931, it is a court of general jurisdiction.

5. Ra is subject to personal jurisdiction in Pennsylvania.

6. Montgomery County is a proper venue for this action under Pennsylvania Rule of Civil Procedure 2179 because the cause of action arose in this county.

7. This action is not subject to compulsory arbitration under 42 Pa. C.S.A. § 7361 and Montgomery County Local Rule of Civil Procedure 1301 because Plaintiffs seek only declaratory relief.

Nature Of The Case

8. This case arises because on August 22, 2018, counsel for Ra sent Strata a formal "cease and desist" letter, threatening litigation if Strata did not "cease and desist" from "its" allegations of patent infringement by Ra and affirmatively retract those allegations.

9. Strata denies that it has made any allegations of patent infringement that are actionable as alleged by Ra, and Strata and Mr. Geiger deny that any statements that Mr. Geiger made in a May 22, 2018 email are actionable at law.

10. Because there is an actual and justiciable controversy between the parties, Strata seeks a declaratory judgment pursuant to Rule 1601 of the Pennsylvania Rules of Civil Procedure and Pennsylvania's Declaratory Judgments Act, 42 Pa. C.S.A. §§ 7531 *et seq.*

11. A declaratory judgment is both necessary and proper to determine the rights and obligations of the parties.

12. A declaratory judgment will terminate the controversy between the parties.

13. As a result, Strata respectfully requests that the Court declare the rights and obligations of the parties with regard to the specific disputes identified below.

The PhotoMedex Litigation and Settlement

14. In 2003 through 2009, Ra and PhotoMedex litigated seven different actions in state and federal courts in California and Illinois.

15. Neither patent infringement by Ra nor off-label marketing by Ra was alleged or addressed in any of those actions.

16. On May 13, 2011, Ra and PhotoMedex entered into a confidential Settlement and Release Agreement ("**Settlement Agreement**").

17. The Settlement Agreement, which is not attached here because it is confidential, provides that it binds "the Parties and their respective legal representatives, and their successors and assigns by operation of law."

18. The Settlement Agreement further provides that the United States District Court for the Southern District of California ("**California Federal Court**") retains jurisdiction over an "action, suit or proceeding with respect to" the Settlement Agreement. Settlement Agreement § 18(b).

19. Thus, by its terms, the Settlement Agreement provides that the California Federal Court only retains jurisdiction for disputes between the parties to that agreement, as well as their successors, and for claims "with respect to" the Settlement Agreement.

20. As explained in more detail below, the present controversy between Ra, on the one hand, and Plaintiffs, on the other, is not subject to the dispute resolution process set forth in the Settlement Agreement because: (a) Strata is not a successor to PhotoMedex; and (b) Ra's current, unfounded allegations do not arise "with respect to" the Settlement Agreement.

21. Moreover, the statements about which Ra complains are not actionable and, therefore, any such claims by Ra would be frivolous notwithstanding its threat of litigation.

Strata's Acquisition Of Certain Assets Of PhotoMedex

22. In June 2015, Strata purchased the assets related to a discrete line of business of PhotoMedex, its XTRAC and VTRAC Dermatology business, for $42.5 million.

23. Strata did not purchase all of the assets related to an entire line of business from PhotoMedex, as certain foreign subsidiary operations were not purchased by Strata.

24. At the time, Strata was known as Mela Sciences, Inc., prior to rebranding as Strata in December 2015.

25. Strata is not a successor or assign of PhotoMedex under Pennsylvania law.

26. There is no continuity of ownership between PhotoMedex and Strata.

27. PhotoMedex did not cease ordinary business and dissolve as soon as practically and legally possible and, in fact, remains in business today.[1]

28. Strata assumed only certain business-related liabilities of PhotoMedex and did not assume the liabilities ordinarily necessary for the uninterrupted continuation of the business of PhotoMedex.

29. The executive management team of PhotoMedex remained in place following the transaction, and Strata's pre-existing executive management team became responsible for the acquired assets related to the XTRAC laser business.

30. In summary, the transaction between PhotoMedex and Strata was a transaction involving the assets related to a discrete line of PhotoMedex's business which PhotoMedex desired to divest to focus on its remaining skin care line of business. Following the transaction,

[1] PhotoMedex, d/b/a FCA Global Realty, trading on the NASDAQ exchange as PHMD, is an existing public corporation currently engaged in the business of real estate acquisition, development, and management, concentrating primarily on investments in high quality income producing assets, hotel and resort developments, and residential developments. As explained in more detail below, PhotoMedex's prior business operations focused on healthcare and skin care products, but the corporate existence of PhotoMedex never terminated and the entity that previously litigated with Ra remains in existence.

PhotoMedex continued to operate its remaining skin care line of business under the direction of its existing executive management. The two companies, PhotoMedex and Strata, were and remained independent, had no common ownership, and operated under separate and distinct executive management teams. At no time did Strata operate as, or become a legal successor to, PhotoMedex.

Mr. Geiger's Communications With UBS Regarding Ra

31. On May 22, 2018, Mr. Geiger met with John Hagens, who worked at UBS. During that meeting, Ra's potential initial public offering was discussed, and Mr. Hagens invited Mr. Geiger to share his thoughts about Ra.

32. Later that day, Mr. Geiger suggested in an email to Mr. Hagens that UBS conduct its own independent investigation into possible patent infringement and "off-label marketing" by Ra. A true and correct copy of Mr. Geiger's May 22, 2018 email is attached hereto as Exhibit A.

33. In his May 22, 2018 email, Mr. Geiger wrote:

> Was good meeting today. I believe it is my obligation to alert you to some concerning issues regarding the IPO of RA Medical which may result in underwrites liability and effect your brand.
>
> ***Potential Off-Label Marketing***
>
> ***I heard that RA may*** be promoting the DEBRA laser as atherectomy device (and physicians are collecting reimbursement from payer as such) while the FDA clearance is limited to CTO (which presents only at 10% of the antrectomy cases). I am confident you don't want to associate your brand with inaccurate description in a prospectus, potential off-label marketing and improper collection of CMS reimbursement, ***if such indeed exist (and assume you will have your own independent investigation into the same).***

FDA Label "The DABRA Laser System is indicated for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease."

Potential Patent Infringement

Mount Sinai owns the attached three method patents for the use of 308nm Excimer laser in the treatments of Vitiligo.

The patents are very broad and are the disclosure of treating vitiligo @ 308nm.

Promoting educating and training the use of the Pharos device for the treatment of Vitiligo is ***or could be in infringement of the Mount Sinai patents***.

Ra Medical is promoting the use of their devices for the treatment of Vitiligo:

- On their website https://www.ramed.com/dermatology/#indications
- In patient brochures (attached)
- In communication with doctors (attached below)
- In trade shows (see picture attached taken in the recent American Society of Dermatology Meeting)
- Trade promotional materials (see attached)

To the best of my knowledge, Ra Medical were put on notice of this infringement by Mount Sinai as early as September 2017 through multiple communications, yet the company continues promotion the use of this patented method without seeking license to do so from the patent holder. To the best of my knowledge, Strata Skin Sciences is the only licensee of this method which is being used with its XTRAC device.

John, ***I am writing you as a friend and without stating any facts but asking you to be alerted to this potential issues and urge you to have underwrite counsel look into the matter***.

As a side note, with virtually zero relevant "vascular" revenues I can't see how this IPO will result in nothing but significant loss to investors.

Exhibit A (emphases added).

Attached to the May 22, 2018 email were a number of publicly available documents regarding the issues raised in the May 22, 2018 email. *See* Exhibit A.

34. As of May 22, 2018, the date of the email, Mr. Geiger was neither an employee nor an agent of Strata.

Mr. Geiger's Reasonable Basis for Suggesting That UBS Investigate Possible Patent Infringement By Ra

35. Mr. Geiger had a reasonable basis for suggesting that UBS investigate possible patent infringement by Ra.

36. Since at least September 2017, Mt. Sinai School of Medicine ("**Mt. Sinai**") has asserted (in writing to Ra) that Ra was potentially infringing three patents for the use of the 308nm Excimer laser to treat vitiligo, which are held by Mt. Sinai and exclusively licensed to Strata.

37. Mr. Geiger attached to his email the three Mt. Sinai patents, *i.e.*, U.S. Pat. No. 6,979,327 ("'327 patent"), U.S. Pat. No. 7,261,729 ("'729 patent"), and U.S. Pat. No. 8,387,621 ("'621 patent"). Exhibit A.

38. On July 16, 2018, less than two months after Mr. Geiger sent his May 22, 2018 email to Mr. Hagens, Ra conceded its potential patent infringement in a preliminary prospectus to potential investors.

39. In a July 16, 2018 Form S-1 registration statement filed with the SEC, Ra conceded the possibility that: (a) Ra would be sued for patent infringement; and (b) a court would find that Ra had engaged in patent infringement:

> Although we believe that we do not infringe the claims of the '327 patent, the '729 patent, or the '621 patent, nor do we believe that we need a license to the '327 patent, the '729 patent, or the '621 patent in order to freely commercialize our products, ***there is a possibility that a suit claiming infringement of the '327 patent,***

the '729 patent, or the '621 patent will be brought against us, and we cannot assure that a court or an administrative agency will agree with our assessment with regard to non-infringement of the '327 patent, the '729 patent, or the '621 patent.

Ra's Form S-1 dated July 16, 2018, a true and correct copy of which is attached hereto as Exhibit B, at 47 (emphasis added).

40. Ra went on to add that "[i]f it was necessary to obtain a license to the '327 patent, the '729 patent, or the '621 patent and a license was not available on commercially reasonable terms or available at all, ***that could affect our ability to commercialize our products and materially and adversely affect our business***." Exhibit B at 47 (emphasis added).

41. In addition, Ra disclosed to potential investors that as early as 2006, an unidentified third party had proposed that Ra license "three U.S. patents directed to the treatment of vitiligo." Exhibit B at 47.

42. On August 24, 2018, Ra amended its Form S-1 but did not alter the provisions cited and quoted above. A true and correct copy of Ra's Form S-1/A dated August 24, 2018 is attached hereto as Exhibit C. *See* Exhibit C at 47.

Mr. Geiger's Reasonable Basis for Suggesting That UBS Investigate Possible Off-Label Marketing By Ra

43. Mr. Geiger also had a reasonable basis for suggesting that UBS investigate possible off-label marketing by Ra.

44. Off-label marketing is the marketing of a pharmaceutical or medical device for a use that is beyond the scope of the clearance granted by the United States Food and Drug Administration ("**FDA**").

45. In addition to liability as a result of FDA fines and penalties for such activities, off-label marketers may also be subject to liability under the federal False Claims Act if they

knowingly submitted or caused to be submitted a false or fraudulent claim to the United States government for payment or approval. *See* 31 U.S.C. § 3729(a). Such a claimant is liable for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim submitted or paid, plus three times the amount of damages sustained by the government. *Id.*

46. At the time of the May 22, 2018 email, Mr. Geiger was aware that the DABRA laser had been cleared by the FDA for only limited indications.

47. Specifically, Ra's FDA Section 510(k) premarket notification clearance from the FDA, dated May 24, 2017, specifically stated that the laser's "Indications for Use" were limited as follows: "The DABRA Laser System is indicated for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease." A true and correct copy of the 510(k) notification is attached to Mr. Geiger's May 22, 2018 email, *see* Exhibit A.

48. Mr. Geiger was also aware that Ra was promoting the product as a device broadly and generally used for atherectomy procedures, notwithstanding that the FDA had cleared the product only for chronic total occlusions ("**CTO**"), which constitute a small portion of atherectomy procedures.

49. As part of its marketing effort, Ra promoted the device as the "DABRA for Atherectomy."

50. Indeed, Ra also posted a press release on its website on or about May 30, 2017, or just six days after the FDA 510(k) approval, titled "FDA Clears Ra Medical's ***DABRA Atherectomy System*** to Treat PAD." (Emphasis added). *See* Ra url: https://www.ramed.com/fda-clears-ra-medicals-dabra-atherectomy-system-to-treat-pad/.

51. Similarly, Ra's S-1 publicly listed the medical billing reimbursement codes it suggests are applicable for the DABRA system, and the list includes reimbursement for procedures not cleared by the FDA for the product.

52. Moreover, Ra continues to market and promote the DABRA system as a general atherectomy product. Ra's most recent S-1 filing for its intended initial public offering, as of the date of the filing of this complaint, states that "DABRA includes a portable excimer laser system combined with proprietary, single-use catheters that together represent a competitive ***atherectomy solution*** for the minimally invasive endovascular treatment of blockages in the vasculature, or blood vessels such as arteries or veins." (Emphasis added).

53. The concern regarding potential off-label liability based upon the foregoing is heightened as a result of Ra's acknowledgement that physicians were using the product for off-label purposes. In fact, Ra acknowledged this fact in its S-1 filings with the SEC.

54. Consequently, Mr. Geiger reasonably believed that Ra's marketing and promotion of its DABRA laser might constitute off-label marketing in violation of FDA regulations and guidance and was worthy of further investigation.

Accelmed's Investment In Strata

55. On May 29, 2018, Strata completed the sale and issuance of 15,740,741 shares of its common stock to a group of investors led by Accelmed for approximately $17 million.

56. Upon the closing of the transaction, Mr. Geiger became Chairman of Strata's Board of Directors.

Ra Threatens Litigation Against Both Strata and Mr. Geiger

57. Within a week of the closing of the Accelmed investment in Strata, Ra's Chief Executive Officer, Dean Irwin, sent a message to Mr. Geiger on "LinkedIn" on June 4, 2018. A

true and correct copy of Mr. Dean's June 4, 2018 LinkedIn message is attached hereto as Exhibit D.

58. Mr. Irwin wrote:

> Hi Uri, I pegged you as a very smart guy. I suppose you're just educated. ***It will be exciting for both of us, perhaps I can school you, as I did your predecessors***, perhaps I'm wrong. I hope you studied well at law. Too bad. We could have helped people together. I guess you're interested in ripping off the consumer, and everyone else as well. I'm sorry you're part of the "Dark Side". ***Let's go! Get ready for a ride, I never give up!*** I suspect you have so much more to lose than me! Dean

Exhibit D (emphases added).

59. On August 22, 2018, although Strata had never made any actionable statements regarding patent infringement by Ra, counsel for Ra sent Strata a formal "cease and desist" letter, threatening litigation if Strata did not "cease and desist" from allegations of patent infringement by Ra and affirmatively retract "its" allegations. A true and correct copy of the August 22, 2018 letter without its voluminous attachments is attached hereto as Exhibit E.

60. In his letter, Ra's lawyer threatened to initiate litigation on behalf of Ra against Strata: "Unless Ra Medical receives confirmation in writing that STRATA Skin Sciences has complied with this demand, accompanied by copies of the correspondence sent by STRATA Skin Sciences retracting its allegations by on or before close of business PDT September 4, 2018, Ra Medical will be contacting Judge Bencivengo, District Judge for the United States District Court for the Southern District of California to enforce the Release Agreement." Exhibit E.

61. Ra's lawyer did not identify any provision of the Settlement Agreement that had been breached by either PhotoMedex or Strata or any claim against Ra that PhotoMedex or Strata had released. Exhibit E.

Ra Cannot Enforce The Settlement Agreement Against Strata

62. Because Strata is neither: (a) a party to the Settlement Agreement; nor (b) a successor or assign of PhotoMedex, Ra cannot "enforce the Release Agreement" against Strata.

63. Because any dispute regarding Mr. Geiger's May 22, 2018 email does not arise out of or relate to facts, events, occurrences or omissions up to and including the date of the Settlement Agreement, it was not addressed by, or released in, the Settlement Agreement.

64. Because any dispute regarding Mr. Geiger's May 22, 2018 email is not an "action, suit or proceeding with respect to" the Settlement Agreement, Ra cannot initiate litigation against Strata pursuant to the Settlement Agreement in the United States District Court for the Southern District of California.

COUNT I – REQUEST FOR DECLARATORY RELIEF

65. Plaintiffs incorporate by reference each of the preceding paragraphs as if set forth in full herein.

66. The parties disagree on at least the following issues: (1) whether Plaintiffs are liable to defendant for any reason, including but not limited to claims of tortious interference, defamation, libel, or unfair competition, or otherwise tortiously interfered with Ra's initial public offering, or engaged in any other wrongdoing, as a result of statements made in Mr. Geiger's May 22, 2018 email about which Ra has threatened to initiate litigation against Strata; (2) whether Plaintiffs made any actionable statements to UBS Investment Bank regarding Ra; (3) whether Strata is a successor or assign of PhotoMedex and therefore subject to the Settlement Agreement; (4) whether any dispute regarding Mr. Geiger's May 22, 2018 email arises out of or relates to facts, events, occurrences or omissions up to and including the date of the Settlement

Agreement; and (5) whether any dispute regarding Mr. Geiger's May 22, 2018 email is an "action, suit or proceeding with respect to" the Settlement Agreement.

WHEREFORE, Plaintiffs request that the Court declare that:

(1) Plaintiffs are not liable to defendant for any reason, including but not limited to claims of tortious interference, defamation, libel, or unfair competition and did not otherwise tortiously interfere with Ra's initial public offering, or engage in any other wrongdoing, as a result of statements made in Mr. Geiger's May 22, 2018 email about which Ra has threatened to initiate litigation against Strata;

(2) Plaintiffs made no actionable statements to UBS Investment Bank regarding Ra;

(3) Strata is not a successor or assign of PhotoMedex and therefore Ra cannot enforce its Settlement Agreement with PhotoMedex against Strata;

(4) any dispute regarding Mr. Geiger's May 22, 2018 email does not arise out of or relate to facts, events, occurrences or omissions up to and including the date of the Settlement Agreement, and therefore such a dispute was not addressed by, or released in, the Settlement Agreement;

(4) any dispute regarding Mr. Geiger's May 22, 2018 email is not an "action, suit or proceeding with respect to" the Settlement Agreement; and

(5) Plaintiffs are awarded such further relief the Court deems appropriate.

Respectfully submitted,

Dated: August 30, 2018 STEVENS & LEE, P.C.

By: */s/ Joseph Wolfson*
Joseph Wolfson
Attorney Id. No. 44431
Neil C. Schur
Attorney Id. No. 79068

1818 Market Street, 29th Floor
Philadelphia, PA 19103
Ph: (215) 751-1249/1944
Fax: (610) 988-0808
Email: jwo@stevenslee.com
ncsc@stevenslee.com

Attorneys for Plaintiffs Strata Skin Sciences, Inc. and Uri Geiger

VERIFICATION

I, Uri Geiger, verify that I am authorized to make this verification on behalf of all Plaintiffs. The foregoing Complaint is based upon facts of which I have personal knowledge, information from business records, or information furnished by employees or representatives of Strata Skin Sciences, Inc. The facts set forth in the foregoing document are true and correct to the best of my knowledge, information and belief. I understand that the statements herein are made subject to the penalties under 18 Pa. C.S.A. § 4904 relating to unsworn falsification to authorities.

Dated: August 30, 2018 /s/Uri Geiger

Uri Geiger

VERIFICATION

I, Dolev Rafaeli, verify that I am authorized to make this verification on behalf of all Plaintiffs. The foregoing Complaint is based upon facts of which I have personal knowledge, information from business records, or information furnished by employees or representatives of Strata Skin Sciences, Inc. The facts set forth in the foregoing document are true and correct to the best of my knowledge, information and belief. I understand that the statements herein are made subject to the penalties under 18 Pa. C.S.A. § 4904 relating to unsworn falsification to authorities.

Dated: August 30, 2018 /s/Dolev Rafaeli

Dolev Rafaeli

EXHIBIT A

From: Uri Geiger
Sent: Tuesday, May 22, 2018 9:45 PM
To: john.hagens@ubs.com
Subject: Meeting at UBS Conf

John,

Was good meeting today. I believe it is my obligation to alert you to some concerning issues regarding the IPO of RA Medical which may result in underwrites liability and effect your brand.

Potential Off-Label Marketing

I heard that RA may be promoting the DEBRA laser as atherectomy device (and physicians are collecting reimbursement from payer as such) while the FDA clearance is limited to CTO (which presents only at 10% of the antrectomy cases). I am confident you don't want to associate your brand with inaccurate description in a prospectus, potential off-label marketing and improper collection of CMS reimbursement, if such indeed exist (and assume you will have your own independent investigation into the same).

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Ra Medical is promoting the use of their devices for the treatment of Vitiligo:

- On their website https://www.ramed.com/dermatology/#indications
- In patient brochures (attached)
- In communication with doctors (attached below)
- In trade shows (see picture attached taken in the recent American Society of Dermatology Meeting)
- Trade promotional materials (see attached)

To the best of my knowledge, Ra Medical were put on notice of this infringement by Mount Sinai as early as September 2017 through multiple communications, yet the company continues promotion the use of this patented method without seeking license to do so from the patent holder. To the best of my knowledge, Strata Skin Sciences is the only licensee of this method which is being used with its XTRAC device.

John, I am writing you as a friend and without stating any facts but asking you to be alerted to this potential issues and urge you to have underwrite counsel look into the matter.

As a side note, with virtually zero relevant "vascular" revenues I can't see how this IPO will result in nothing but significant loss to investors.

Uri

accelmed
Building Medical Device Companies

Dr. Uri Geiger
Managing Partner
Office (212) 554-4601
Cell: (917) 270-2452
uri@accelmed.com
www.accelmed.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 24, 2017

Ra Medical Systems, Inc.
Mr. Dean Irwin
CEO
1930 Kellogg Ave.
Carlsbad, CA 92008

Re: K170349
Trade/Device Name: DABRA Laser System (DABRA Laser model RA-308 and DABRA Catheter model 101)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: April 24, 2017
Received: April 24, 2017

Dear Mr. Irwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170349

Device Name
DABRA Laser System (DABRA Laser model RA-308 and DABRA Catheter model 101)

Indications for Use *(Describe)*
The DABRA Laser System is indicated for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PREMARKET NOTIFICATION

TRADITIONAL 510(k) SUMMARY

Submitter Information

A. Company Name: Ra Medical Systems, Inc.
B. Company address: 1930 Kellogg Ave, Carlsbad CA 92008
C. Company Phone: (760) 804 1648 / (877) 635 1800 Fax: (760) 804 1657
D. Contact Person: Dean Irwin, Chief Executive Officer
E. Date Prepared: January 20, 2017

Device Identification

A. Device Trade Name: DABRA Laser System (DABRA Laser model RA-308 and DABRA Catheter model 101)
B. Device Common Name: Laser Catheter, Excimer Laser
C. Classification Name: Percutaneous catheter
D. Device Class: Class II (per 870.1250 percutaneous catheter)
E. Device Code: PDU

Identification of Predicate Device

Spectranetics CLiRpath Laser Catheters; K040067.

Identification of Reference Devices

Ra Medical EX-308; K062963

Spectranetics CVX-300; K052514

Device Description

Ra Medical Systems is requesting FDA 510(k) clearance for the DABRA Laser (model RA-308) and DABRA™ Catheter (model 101) as a system, collectively the DABRA Laser System™.

The Ra Medical Systems' DABRA Laser System™ is composed of a laser light source and catheter consisting of optically conducting fluid encased in medical grade tubing enclosed by an optical window on either end. The tip and the fluid conduct the ultraviolet laser energy from the laser light source to the distal tip of the catheter. The laser light is generated by a 308nm excimer source. The catheter is connected to the laser for the procedure, and then inserted into the patient's vasculature, allowing the physician to target the laser energy to a blockage or lesion. Patient contacting parts of the device are the distal tip (titanium), the distal tip window (glass), the glue for the distal tip (epoxy), and the catheter tube (FEP). These parts are limited (<24 hours) blood contact. The laser energy photoablates the lesion material creating a lumen that permits blood flow, and allows access for other interventional treatment devices, such as balloons. The system is designed to be used in a catheterization laboratory. The candidates for this type of laser treatment are people who have blockages in their leg arteries that completely obstruct flow (chronic total occlusions). Flow obstruction of this type causes pain, wounds that do not heal, gangrene and ultimately limb amputation.

Intended Use (807.92(a)(5))

For use in ablating a channel in occlusive peripheral vascular disease.

Indications for Use

The DABRA Laser System is indicated for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease.

Comparison to Predicate Devices

The DABRA Laser™ and DABRA Catheter™ use the same materials (plastics, glass, metal), the same light source and energy (308nm excimer at 15mJ), the same constructions, and the same interventional techniques (step-by-step) to operate as the predicate device. The differences between the devices include a more compact excimer source and an optically conducting material as opposed to a continuous glass element. The materials that define the laser output as well as the materials that contact the patient are all either identical, or are substantially equivalent in regards to the interaction of the device with the patient or the operator. The DABRA Catheter™ is 1.5mm in diameter whereas the predicate device is for a line of different sized catheters ranging from .9mm to 2.5mm. The device that is closest in diameter is the CLiRpath 1.4mm device, which was the subject of comparison bench tests. The DABRA Catheter™ has a working length of 150cm.

The RA-308 light source for the device is nearly identical to the EX-308, with different delivery device connections and software. The RA-308 Laser is identical to the EX-308 in fit, form, function, energy type, materials, and use.

The Spectranetics CVX-300 reference device also has an 80Hz repetition rate and continuous operation.

The DABRA Laser™ and DABRA Catheter™ were bench tested using a wide variety of protocols. These protocols also included side-by-side performance tests. The direct comparison tests included:

a. Energy output
b. Output fluence in mJ/mm^2 applied to the target
c. Beam divergence and beam profile
d. Energy transmission in test models
e. Ablation though non-biological samples to demonstrate hole size and features
f. Ablation through biological materials (in vitro porcine)
g. Vasculature maneuverability in test models
h. Insertion and retraction force, at time of manufacture and aged 2 years

Other bench tests on sterilized catheters (where applicable) include:

a. Pull testing, at time of manufacture and aged 2 years
b. Corrosion resistance

c. Patent artery perforation testing
d. Kink testing, at time of manufacture and aged 2 years
e. Torque testing, at time of manufacture and aged 2 years
f. Radio opaque tip testing
g. Catheter fluid leak analysis
h. Package integrity validation
i. Process indicator validation
j. Dimensional testing, at time of manufacture and aged 2 years
k. Particulate investigation
l. Simulated use testing

Other testing to show conformance to various standards include:

a. IEC 60601-1 Electrical safety
b. IEC 60825-1 Safety of laser products
c. IEC 60601-2-22 Basic safety and essential performance of laser equipment
d. IEC 60601-1-2 Electromagnetic compatibility
e. 21 CFR 1010 and 1040 Electronic products and light-emitting products
f. ISO 10555 Sterile single-use intravascular catheters
g. IEC 62366 Usability engineering

Biocompatibility and Sterilization

The Ra Medical DABRA Catheters™ are manufactured from materials and components that are commonly used in other catheters already marketed. All of the materials conform to ISO 10993, Biological Evaluation of Medical Devices. The following biocompatibility testing has been performed:

- C3a complement activation
- Cytotoxicity
- Guinea pig maximization sensitization
- Direct and indirect hemolysis
- Intracutaneous reactivity
- Partial thromboplastin time
- Material-mediated Pyrogenicity
- SC5b-9 complement activation
- Acute systemic toxicity
- In vivo human thrombus evaluation

Ra Medical conducts and maintains valid gamma radiation sterilization processes in conformance with ISO 11137 Sterilization of Health Care Products – Radiation. The packaging for the DABRA Catheters™ has been initially validated, and each is visually inspected prior to delivery to finished goods. A shelf life of 1 year was validated based on successful packaging integrity and product performance testing using accelerated aged and real time aged device samples.

Each catheter is inspected and 100% tested for dimensions and functionality. It has been validated for integrity to conform to ISO 10555-1 Sterile Single-Use Intravascular Catheters.

Clinical Results

The device was used on 50 patients (66 lesions) in two studies to determine that the device is substantially equivalent to the predicate in terms of procedure outcome, adverse events, and physician use. The performance goal was exceeded.

a. the device deployed properly and predictably from the packaging,

b. the device navigated the vasculature easily,

c. the device crossed the lesions with the predicted manner, time and ease,

d. the outcome of the procedure was as predicted,

e. the follow-up on the patients revealed no undesired effects,

f. there were no observed adverse events or safety issues according to the study protocol.

Conclusion

The analysis, testing, and clinical study establish the substantial equivalence between the Ra Medical Systems DABRA Laser™ and DABRA Catheter™ and the predicate device, and demonstrate that the device performs equivalently to the referenced predicate and exceeded the performance goal.

US008387621B2

(12) **United States Patent**
Spencer

(10) **Patent No.: US 8,387,621 B2**
(45) **Date of Patent: *Mar. 5, 2013**

(54) **TREATMENT OF VITILIGO**

(75) Inventor: **James M. Spencer**, St. Petersburg, FL (US)

(73) Assignee: **Mount Sinai School of Medicine**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/785,352**

(22) Filed: **May 21, 2010**

(65) **Prior Publication Data**

US 2010/0234926 A1 Sep. 16, 2010

Related U.S. Application Data

(63) Continuation of application No. 11/696,460, filed on Apr. 4, 2007, now abandoned, which is a continuation of application No. 11/174,437, filed on Jul. 1, 2005, now Pat. No. 7,261,729, which is a continuation of application No. 09/790,786, filed on Feb. 22, 2001, now Pat. No. 6,979,327.

(60) Provisional application No. 60/184,971, filed on Feb. 25, 2000.

(51) **Int. Cl.**
A61B 19/00 (2006.01)

(52) **U.S. Cl.** **128/898**; 606/3; 606/9; 607/89

(58) **Field of Classification Search** 606/3, 9; 607/88–91, 94; 128/898
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,103,175	A	7/1978	Levin	
4,558,700	A	12/1985	Mutzhas	
4,674,507	A	6/1987	Basso	
5,217,455	A	6/1993	Tan	
5,312,395	A	5/1994	Tan et al.	
5,433,942	A *	7/1995	Wood et al.	424/59
6,017,360	A	1/2000	Chubb et al.	
6,323,219	B1	11/2001	Costanzo	
6,413,268	B1	7/2002	Hartman	
6,436,127	B1 *	8/2002	Anderson et al.	607/89
6,979,327	B2 *	12/2005	Spencer	606/9
7,261,729	B2 *	8/2007	Spencer	607/89
2003/0113540	A1	6/2003	Anderson et al.	

OTHER PUBLICATIONS

Asawanonda, P., et al., "308-nm Excimer laser for the treatment of psoriasis" A dose response study, Arch Dermatol, 136:619-624 (2000).

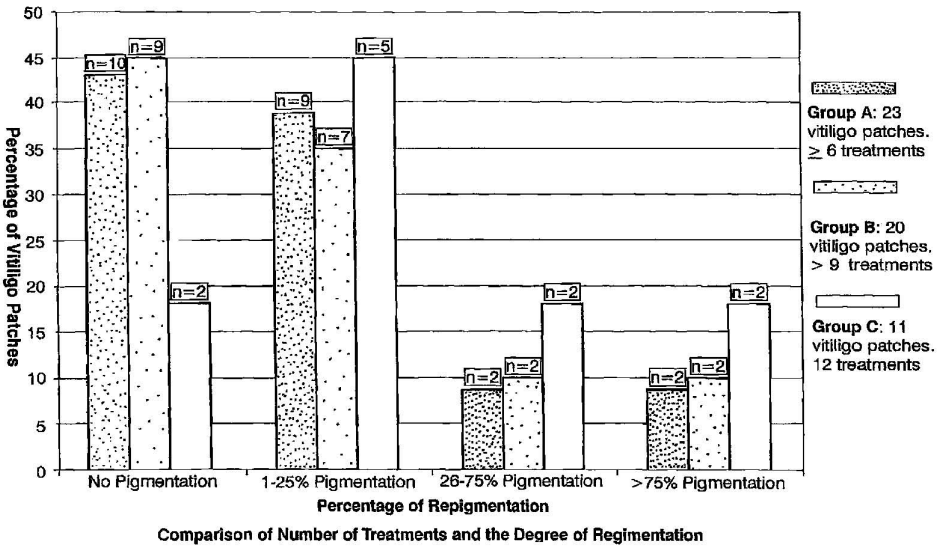
(Continued)

Primary Examiner — Ahmed Farah
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

Disclosed herein is a novel method of treating vitiligo by using an excimer laser that emits light in the UVB range. The invention includes a method of incrementally increasing exposure of affected vitiligo areas with UVB laser light from an excimer laser to restore pigmentation to skin areas afflicted with vitiligo.

6 Claims, 7 Drawing Sheets



Comparison of Number of Treatments and the Degree of Regimentation

OTHER PUBLICATIONS

Bossuyt et al., "the Development of Guidelines for the Treatment of Vitiligo," Arch Dermatol, vol. 135 (Dec. 1999).

Elliott, J., et al., "Clinical experiences with methosxalen in the treatment of vitiligo," J. Invest Dermatol, 2:311-14 (1959).

Farah, F., et al., "The treatment of vitiligo with psoralens and triamcinolone by mouth," BR J. Bermatol, 79-89-91 (1967).

T.M. Lotti et al., "UV-B radiation microphototherapy. An elective treatment for segmental vitiligo.", J. Eur. Acad. Dermatol. Venereol. 13, pp. 102-108 (1999).

Njoo, MD et al., "The development of guidelines for the treatment of vitiligo," Arch Dermatol, 135, 1514-21 (1999).

Njoo, MD et al., "Nonsurgical repigmentation therapies in vitiligo," Arch Dermatol, 134:1532-40 (1998).

Njoo, MD., et al., "Treatment of generalized vitiligo in children with narrow-band (TL-01) UVB radiation therapy," J Am Acad Dermatol, 42:245-53 (2000).

Ohshiro, T., "Laser treatment of vitiligo" Amer Society of Laser Med. And Surgery Abstracts, 123:98.

Ortonne, J., "Psoralen therapy In Vitiligo," Clin Dermatol, 7:120-35 (1989).

Preston, DS, Stern, RS, "Nonmelanoma cancers of the skin," N. Engl. J. Med. 327:1649-62 (1992).

Sasaki K., Ohshiro T., "Role of low reactive-level laser therapy (LLLT) in the treatment of acquired and cicatrical vitiligo," Laser Therapy, 1:141-146 (1989).

Stern, RS, Lang, R., "Non-melanoma skin cancer occurring in patients treated with PUVA five to ten years after first treatment," J. Invest Dermatol, 91:120-4 (1989).

Thissen, M., MD and Westerhof, W., MD, "Laser Treatment for further depigmentation in vitiligo," Pharmacology and Therapeutics, 36:386-3388 (1997).

Westerhof et al., "Treatment of Generalized Vitiligo in Children with Narrow-band (TL-01) UVB Radiation Therapy," J AM ACAD Dermatol, vol. 42, 2, pp. 245-253 (Feb. 2000).

Westerhof, W., et al., "Treatment of Vitiligo with UV-B radiation vs Topical psoralen plus UV-A," Arch Dermatol, 133:1525-28 (1997).

Yu H., Wu, M., Kao Y., Wu, C., Helium-neon laser treatment induces repigmentation in segmental-type vitiligo, Journ of Invest Dermatol Abstracts 526.

* cited by examiner

Figure. 1

Figure. 2

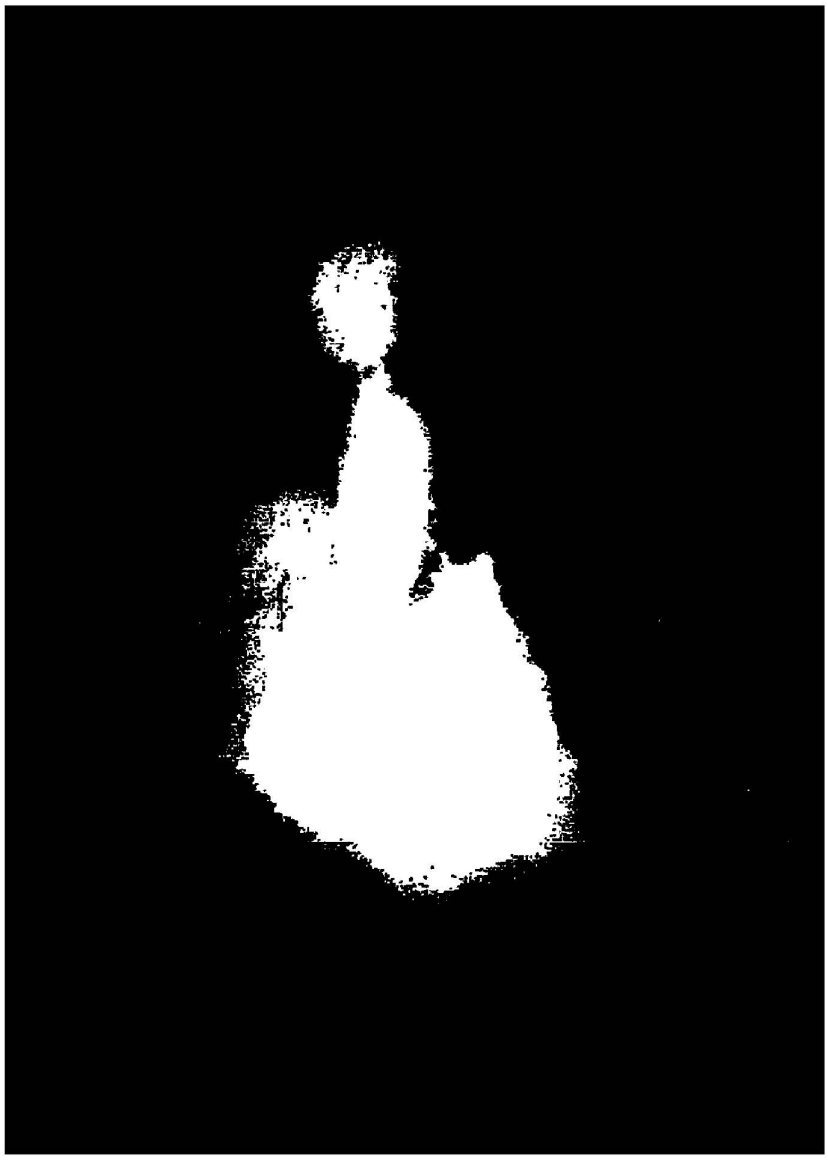
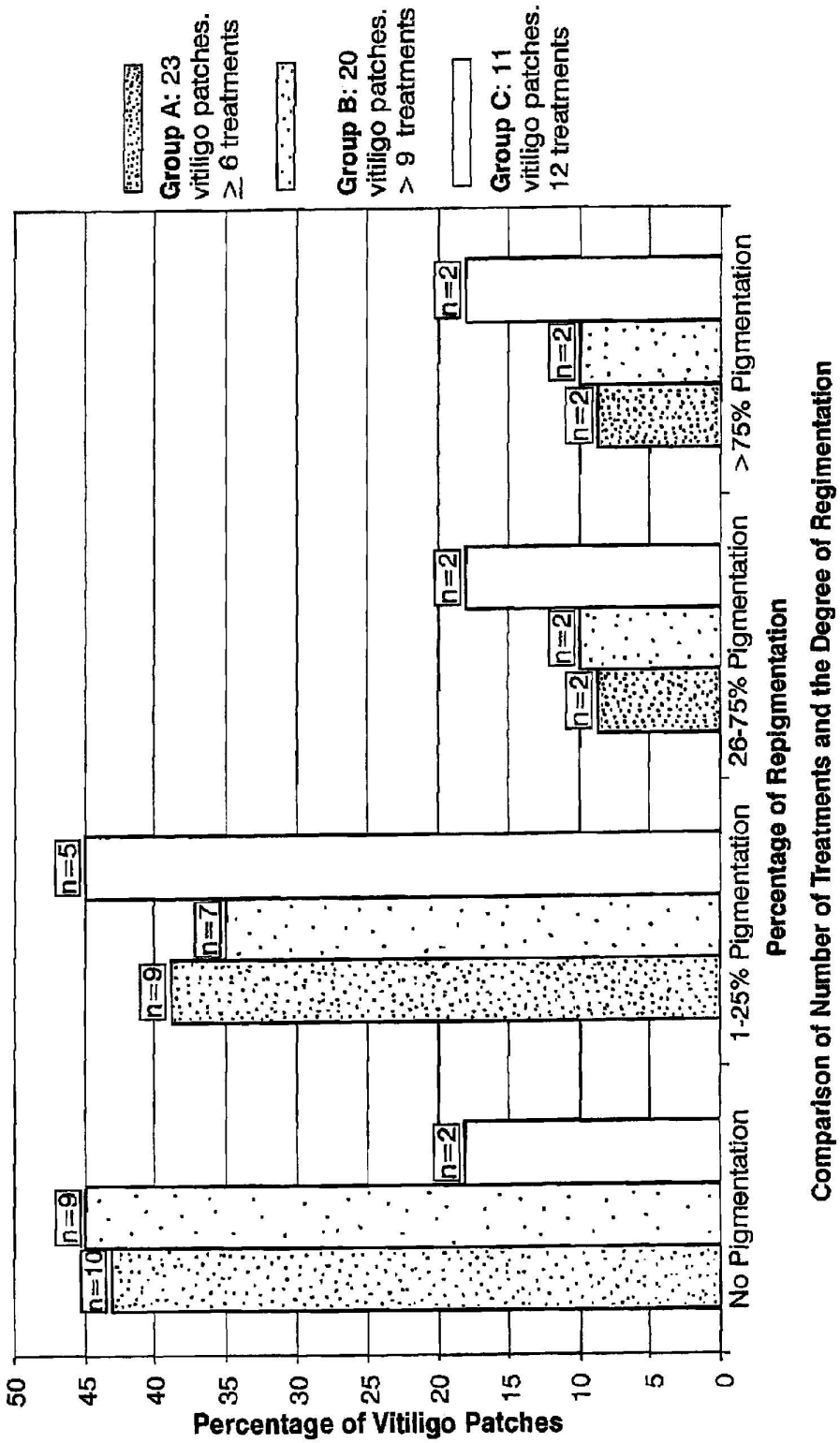


Figure. 3



Comparison of Number of Treatments and the Degree of Regimentation

Figure 4

Figure. 5

Figure. 6

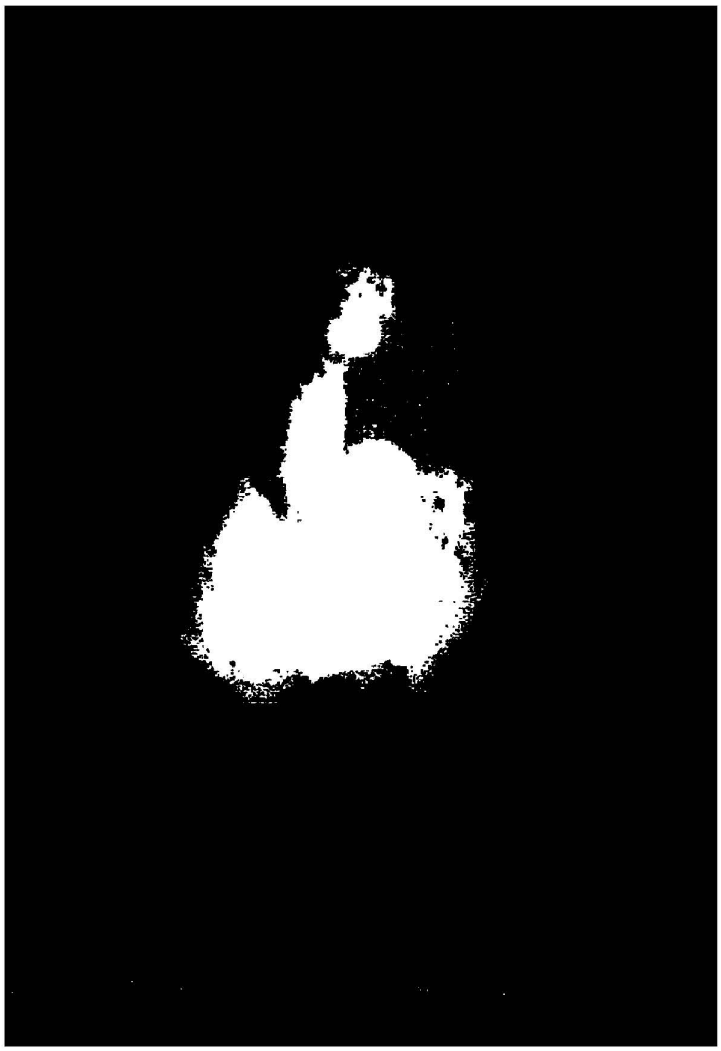
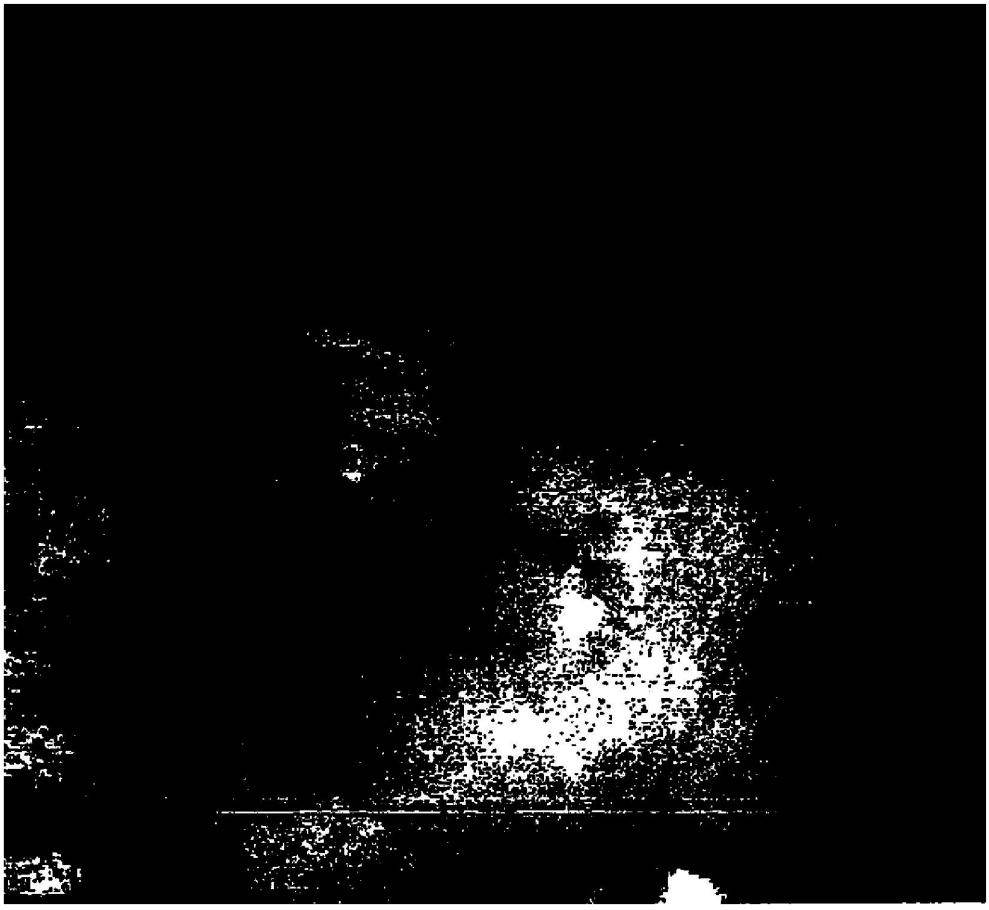


Figure. 7



TREATMENT OF VITILIGO

This application is a continuation of U.S. patent application Ser. No. 11/696,460, filed Apr. 4, 2007, which is a continuation of U.S. patent application Ser. No. 11/174,437, filed Jul. 1, 2005, now U.S. Pat. No. 7,261,729, which is a continuation of U.S. patent application Ser. No. 09/790,786, filed Feb. 22, 2001, now U.S. Pat. No. 6,979,327, which claims priority under 35 U.S.C. §119 from U.S. Provisional Application Ser. No. 60/184,971, filed Feb. 25, 2000, each of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

Vitiligo is a cutaneous disease in which there is a complete loss of pigment in localized areas of the skin. This loss of pigment results in the effected areas being completely white. This condition has a predilection for the skin around the mouth and eyes. The result is cosmetically disfiguring, especially for dark skinned people. Furthermore, the depigmented skin is sun sensitive, and thus is subject to sunburns and skin cancer. In sum, vitiligo is both cosmetically and practically distressing to patients afflicted with the disease.

In normal skin, varying shades of brown are seen (depending on a person's race) representing the pigment melanin. This pigment is produced by a cell type known as a melanocyte. In vitiligo, there is an absence of melanocytes in the areas afflicted with the disorder. An absence of melanocytes results in an absence of melanin pigment, and thus the melanin-free area is white. Normal skin responds to ultraviolet light with an increase in the brown pigment melanin (tanning). Specifically, ultraviolet radiation stimulates melanocytes to proliferate and produce more melanin.

Attempts have also been made to "tan" vitiligo areas using ultraviolet light treatments. The ultraviolet spectrum is divided into two portions, "UVA" and "UVB," which is light of 320-400 nm and 290-320 nm in wavelength, respectively. UVB is much more effective at producing a tan in normal skin. In normal skin, melanocytes reside in the epidermis, which is the outer layer of the skin. The epidermis is only 0.1 mm thick, so the melanocytes are very near the surface. UVB radiation can only penetrate to about 0.1 mm, but this is sufficient to reach the melanocytes. In patients with vitiligo, these epidermal melanocytes are gone. In some cases, there are surviving melanocytes deeper in the skin down the hair follicles. These melanocytes may be several millimeters deep. UVB cannot penetrate this deep in the skin to stimulate these surviving deep melanocytes. Exposure to UVB results in a sunburn at the surface of the skin with no stimulation of these deep melanocytes. Thus attempts to repopulate the vitiligo areas with melanocytes deep in the skin in response to UVB exposure have failed. UVA will penetrate a bit deeper in the skin than UVB. However, UVA is very poor at stimulating melanocytes to proliferate and migrate.

DESCRIPTION OF RELATED ART

The present invention uses an excimer laser to restore pigmentation to skin areas afflicted with vitiligo, and is an improvement over current treatments for vitiligo. Currently, treatments for vitiligo suffer from a number of drawbacks. For instance, Fitzpatrick's Dermatology in General Medicine, Vol. 1, Chapter 89 (5th ed., I. M. Freedberg et al., eds., 1999) teaches the use of sunscreens and cosmetic cover-ups including dyes and conventional makeup as a way to mask skin areas afflicted with vitiligo. However, the ability of sunscreens to minimize contrast between normal skin and vitiligo-afflicted areas has been disappointing. Sunscreens, as well as cosmetics and dyes, are not permanent. These products tend to rub-off and have been of limited value in areas such as the lower neck, wrists and hands. In addition, unlike the present invention, sunscreens and cosmetics cover-ups do not attempt to treat vitiligo, but simply blend in the affected areas with the surrounding skin. The prior art also teaches the use of topical glucocortoids to treat isolated areas of vitiligo. Fitzpatrick's Dermatology in General Medicine. However, the overall results tend to be disappointing. The present invention improves on these treatments by providing a more permanent restoration of pigmentation to vitiligo affected areas, with a relatively high rate of success.

Another known treatment for vitiligo attempts to increase the action of UVA light by combining exposure to UVA with a chemical that is applied to the skin to increase sensitivity to UVA. Fitzpatrick's Dermatology in General Medicine, Vol. 1, Chapter 89 (5th ed., I. M. Freedberg et al., eds., 1999). This chemical is known as psoralen, and psoralen and UVA together are known as PUVA. Specifically, high output UVA (320-400 nm) light bulbs are utilized within an indoor phototherapy unit. The patient applies psoralen to the effected areas, then stands inside the phototherapy unit for exposure to the UVA light emitted by conventional tube-style bulbs.

This type of PUVA treatment suffers from a number of drawbacks. Unlike the present invention, PUVA treatment is to the whole body, not just the vitiligo areas. Therefore PUVA therapy has been associated with the development of skin cancers. PUVA treatment is also time-consuming; a minimum of 100 treatments, given 2-3 times per week over many months, is necessary before any response is seen. In addition, this treatment has had a relatively low success rate. Significantly less than 50% of patients will respond to this treatment. The present invention, however, treats only those skin areas afflicted with vitiligo, and thus minimizes the risk of skin cancer. The present invention also is less time consuming, and enjoys a relatively higher success rate.

Topical PUVA also may be used to treat localized patches of vitiligo and consists of applying a topical preparation of 8-methoxypsoralen to the patch of vitiligo and exposing the patch to UVA radiation at intervals of two to three times weekly. This type of PUVA treatment also has a number of drawbacks. Erythema, blistering and hyperpigmentation of surrounding skin are common complications. In addition, the success rate is relatively low. Repigmentation is seen in only about half of treated patients. Westernof, W., et al., "Treatment of Vitiligo with UV-B Radiation vs. Topical Psoralen Plus UV-A," *Arch. Dermatol;* 1997; 133:1525-28.

Phototherapy with UV-A radiation and oral psoralens is another known treatment. UV-A irradiation occurs at intervals of two to three times weekly and is generally maintained for months to greater than a year. Once again, the success rate is relatively low. Elliott, J., "Clinical Experiences With Methosaxalen in the Treatment of Vitiligo", *J. Invest Dermatol;* 1959; 32: 311-314; Farah, F. et al, "The Treatment of Vitiligo with Psoralens and Triamcinolone By Mouth", *Br. J. Dermatol;* 1969; 79: 89-91; Ortonne J., "Psoralen Therapy in Vitiligo", *Clin. Dermatol;* 1989; 7:120-135. Moreover, side effects of this type of PUVA include burning, nausea, erythema, lentigenes, pruritus, and cataracts.

UVB phototherapy is much more effective at stimulating melanocytes than PUVA. However, regular UVB light cannot penetrate the skin deeper than the epidermis, and hence is completely ineffective in stimulating the deep melanocytes underneath patches of vitiligo. The present invention overcomes this problem in the prior art through the use of an

excimer laser which emits laser light in the ultraviolet range and provides higher energy fluences thereby decreasing the treatment time.

M. Thissen et al., Laser Treatment for Further Depigmentation in Vitiligo, International Journal of Dermatology, Vol. 36 (1997) teaches the use of a ruby laser to depigment normal skin and bleach it to a white color. Ruby lasers, unlike excimer lasers, employ a ruby crystal to generate laser light in the red spectrum. The laser light is used to depigment normal skin, and does not attempt to restore or treat skin areas afflicted by vitiligo. Therefore, unlike the present invention which attempts to stimulate melanin production and restore pigmentation, patients subjected to the Thissen treatment end up depigmenting their remaining normal skin. The drawbacks of this treatment are that the depigmented skin lacks melanin and is the color white, which is generally less aesthetically desirable than the natural skin color of the patient. This depigmented skin is also more sensitive to the sun than normally pigmented skin, and the patient with depigmented skin must be protected from the sun for the rest of his or her life. Finally, the Thissen article acknowledges that this method is only effective in vitiligo afflicted patients where the skin has become over 80% depigmented.

K. Sasaki et al., Role of Low Reactive-Level Laser Therapy (LLLT) in the Treatment of Acquired and Cicatrical Vitiligo, Laser Therapy, Vol. 1 No. 3 (1989) teaches use of a diode laser, either alone or in combination with an argon laser, to revive dormant or malfunctioning melanocytes in order to repigment vitiligo afflicted skin areas. This technique suffers from the disadvantage that both the argon and diode lasers are needed in order to treat cicatrical-type vitiligo, or vitiligo that follows after scarring or trauma. Argon lasers also suffer from the disadvantage that they may cause thermal damage to the skin. In addition, argon lasers as disclosed in Sasaki emit visible light (488 nm and 514.5 nm), while diode lasers emit infrared light (830 nm). Unlike the present invention, these lasers-do not emit UV light, and therefore do not benefit from the special ability UVB light has in stimulating melanocyte growth and melanin production.

H. Yu et al., Helium-Neon Laser Treatment Induces Repigmentation in Segmental-Type Vitiligo, Journal of Investigative Dermatology, Vol. 112(4) (1999) teaches use of a Helium-Neon laser that emits light in the visible red to infrared range, as opposed to UV light. Unlike the present invention, Helium-Neon laser light suffers from the disadvantage that it does not stimulate melanocytes directly, but instead induces nerve growth. For this reason, this method of treating vitiligo is confined to segmental-type vitiligo, which is vitiligo caused by dysfunction of nerves.

Lasers have also been used to treat vitiligo to aid in skin grafting. R. Kaufman, et al., Grafting of In Vitro Cultured Melanocytes onto Laser-Ablated Lesions in Vitiligo, ACTA Demato-Veneriologica, Vol. 78/2 (1998); J. S. Yang et al., Treatment of Vitiligo with Autologous Epidermal Grafting by Means of Pulsed Erbium: YAB Laser, Journal of the American Academy of Dermatology, Vol. 38/2 (1998). Unlike the present invention, these techniques are invasive and require that the vitiligo affected areas be relatively small and stable.

Narrowband UV-B phototherapy using a spectrum of 311-315 nm wavelength with a peak emission of 311 nm has been used to treat vitiligo. Westerhof et al. teaches the use of narrowband UV-B phototherapy at intervals of two times per week for four to twelve months. However, this method requires regular phototherapy sessions several times a week for up to a year to achieve a therapeutic response. UV-B phototherapy in general has few side effects and is mainly limited to erythema.

What is needed is a method of treating vitiligo with UVB light that treats only the areas of vitiligo with increased precision, at higher energy fluences, to reduce length of treatment. What is also needed is a method of treating vitiligo that is as effective as UVB light in stimulating melanocytes, but without the disadvantage of being unable to penetrate beyond the epidermal skin layer. What is also needed is a method of treating vitiligo that only treats the areas of the vitiligo, and not the entire body, to reduce the risk of skin cancers. Finally, what is needed is a method that restores pigmentation to skin areas afflicted with vitiligo, rather than simply covering the affected areas or bleaching normal skin white, so that the result is both more permanent and more aesthetically pleasing.

BRIEF SUMMARY OF THE INVENTION

The present invention is a method of treating vitiligo using an excimer laser, a laser which produces light in the UVB range. The present invention includes a method for treating vitiligo by incrementally increasing exposure of afflicted areas of skin with UVB laser light to restore the pigmentation in the areas afflicted with vitiligo. The present invention overcomes the problems associated with current vitiligo treatments through the use of an excimer laser. Laser light is coherent and collimated whereas regular light is incoherent and divergent, allowing laser UVB light to penetrate deeper into skin and quickly stimulate deep melanocytes underneath patches of vitiligo. Therefore unlike regular UVB light or, PUVA therapy, the present invention is able to better stimulate deep melanocytes, and is able to deliver higher energy fluences in less time than known treatments. Another advantage of the present invention is that laser treatment is confined to only those areas afflicted with vitiligo, not to normal skin, and thus significantly reduces risk of skin cancers over other types of therapy such as PUVA treatments. Yet another advantage of the present invention is that the vitiligo areas are treated and made darker, making the areas better match the natural skin color of the patient, as opposed to simply bleaching the surrounding non-vitiligo areas to an unnatural white. Finally, the present invention changes the actual pigment of the skin, and therefore will not rub or wash-off.

BRIEF DESCRIPTION OF THE DRAWINGS

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

FIG. **1** depicts vitiligo involving periocular skin in an individual with phototype V skin before treatment.

FIG. **2** depicts vitiligo involving the extensor elbow in an individual with phototype V skin before treatment.

FIG. **3** depicts vitiligo involving the periocular skin in an individual with phototype III skin before treatment.

FIG. **4** depicts a comparison of the number of treatments and the degree of repigmentation in the study population.

FIG. **5** depicts complete repigmentation after 5 treatments.

FIG. **6** depicts spotty follicular repigmentation after 12 treatments.

FIG. **7** depicts focal repigmentation after 12 treatments.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is a method of using UVB laser light to treat vitiligo. Laser light is different than regular light in that it is coherent and collimated, which can be thought of as

more "concentrated." A given dose of laser light is often much more effective in producing photochemical reactions than conventional light. Treatment of vitiligo with UVB laser light is superior because laser light 1) penetrates deeper in the skin than conventional light, and 2) a given dose of light is delivered much more quickly with laser light. This second effect becomes important if stimulation of melanocytes has a time component, i.e. stimulation is more effective if done quickly.

Also claimed and disclosed is a method of using UVB laser light to treat vitiligo where the time of exposure to the vitiligo afflicted skin areas is gradually increased. A diagnosis of vitiligo is made clinically, and the absence of melanin is confirmed by Woods light examination. A Wood's light examination uses UV light, also known as "black light," to accentuate areas of white color. In the practicing invention, a patient afflicted with vitiligo is treated by exposing the afflicted area to the UVB laser beam at periodic intervals. For example, the exposure to the vitiligo afflicted skin areas can be administered between 1 to 5 times per week. The first treatment would last for up to 5 seconds, depending on the intensity setting of the laser beam. The greater the intensity, the shorter the exposure to the beam. The exposure time for each treatment would be gradually increased, to a maximum of 10 seconds.

In one embodiment of the invention, an excimer laser is used to generate the UVB laser light. An excimer laser is a laser which uses a rare-gas halide or rare-gas metal vapor and emits laser light in the ultraviolet (126 to 558 nm) range. Currently, only excimer lasers emit laser light in the UV range, although any future lasers that emit light in the UVB range would also be encompassed by this invention. The laser used should operate in a range between 290 and 320 nm in wavelength, the UVB range of light. The laser should be utilized at a setting of not more than 120 mwatts.

A 308 excimer laser from the Surgilight Corporation, Winter Park Fla., is preferred for use in practicing the present invention. This laser operates at 308 nm via a fiber optic cable with pulse duration of 120 nsec, fired at repetition rate of 20 hz. The laser spot size is 10×10 mm. A photometer measures laser output, and the laser is utilized at a setting of 60 mwatts. In one preferred method of treatment, a patient with vitiligo is exposed to the 308 nm excimer laser three times a week. The first treatment lasts 2 seconds. The patient returns, and if there is no sunburn, the treated area is retreated again for 2 seconds. If there is sunburn, treatment is withheld until the sunburn is gone. On the third visit, if there is no sunburn, the dose is increased to 4 seconds. This is repeated the fourth visit, and then increased to 6 seconds on the fifth visit. On the sixth visit, 6 seconds is given again. Therefore, in this preferred method, each dose is repeated once, then increased by two seconds, to a maximum of 10 seconds. Treatment is continued for one month, or until repigmentation occurs, which is a much shorter time than PUVA therapy, which typically takes 6 months before any result is seen. Repigmentation is the appearance of brown pigment in the treated area, and is documented by standardized photography. In preliminary trials, four out of five patients receiving treatment for a minimum of nine sessions showed some response. This is a significant and substantial improvement in success rate over PUVA, glucocortoids, or any other current therapy for vitiligo. The repigmented skin is also relatively more permanent than other treatments such as sunscreens and cosmetic cover-ups, and will not rub-off.

When compared to standard phototheraphy, the 308 nm excimer laser has the advantage of having increased precision and the ability to deliver higher energy fluences thereby decreasing treatment time.

EXAMPLES

The following are intended as non-limiting examples of the invention.

Six men and twelve women with multiple discreet chronic stable patches of vitiligo enrolled in the study. Most patients had received and failed a variety of prior therapies for vitiligo (Table 1). No patient received any additional vitiligo therapy for at least one month prior to and during the study.

Eighteen patients started the study with a total of twenty-nine treated vitiligo patches. All patients had untreated vitiligo patches that were used as controls. Test areas of vitiligo were treated using a 308-nm xenon chloride excimer laser. A 120-ns, 20-hz, pulse was used with a 10-mm by 10-mm spot size and a power output of 60 mw of laser light. Lesions were treated three times a week for a maximum of 12 treatments. Exposure time was started at 2 seconds and increased by 2 seconds at every other visit until complete repigmentation occurred or until the protocol (12 treatments) was completed. Treatment was withheld if sunburn was observed and held until resolution.

Treated areas were evaluated for repigmentation and erythema on separate four point scales. Repigmentation was graded on the percentage of treated area of repigmentation as follows: 0:0%, 1:1-25%, 2:26-75% and 3:76-100%. Sunburn (erythema) was similarly graded as follows: 0-None, 1-Mild, 2-Moderate, 3-Severe. Patients with no repigmentation were defined as non-responders.

Results

Twelve patients with 23 patches completed at least six treatments. Six patients with 11 patches of vitiligo completed all twelve treatments that required an average of four weeks to complete. Six patients dropped out of the study before completion of six treatments and resulted in one slight repigmentation and five non-responders. Two of the non-responders developed mild erythema. Twelve patients with six or more total treatments of 23 vitiligo patches resulted in partial repigmentation in 57% of twenty-three patches. Six patients who completed twelve treatments of 11 vitiligo patches resulted in partial repigmentation in 87% of eleven patches (FIG. **4**). There were no serious adverse events. Mild sunburn with persistent erythema lasting up to three weeks was observed in some patients. Patients with the most repigmentation were skin-types III-VI. Table 1 sets forth the results.

TABLE 1

Demographics and Study Results of Patients Involved In the Protocol

Patient	Sex	Skin Phototype	Prior Treatment	Treatment Locations	Treatments Received	% Repigmentation*	Erythema**
1	M	V	TS	Periocular	5	3	0
				Forearm	12	3	0
2	F	III	PUVA	Periocular	12	1	0
				Back	12	1	0
				Hand	12	0	0
				Thigh	12	1	0
3	F	I	None	L. Forearm	12	1	1
4	F	III-IV	None	L. Preauricular	9		
5	M	II	None	L. Neck	3	0	1
6	F	II	TS. Folate	L. Hand	5	1	0
7	F	IV	PUVA	Finger	12	0	0
8	M	II	TS	Abdomen	3	0	1
9	F	VI	TS	R. Temple	2	0	0
10	F	II	None	R. Wrist	6		
11	F	III-IV	None	R. Axilla	8	1	1
				Sternum	8	1	1

TABLE 1-continued

Demographics and Study Results of Patients Involved In the Protocol

Patient	Sex	Skin Photo-type	Prior Treatment	Treatment Locations	Treatments Received	% Repigmentation*	Erythema**
12	F		None	R. Axilla	1	0	0
13	M	III-IV	None	Chin	10	0	1
				L. Elbow	10	0	1
				L. Arm	10	0	1
14	M	II	PUVA	L. periocular	10	0	1
				R. Elbow	10	1	0
				Chin	10	0	1
15	F	II	PUVA	L. Shin	9	1	0
				L. Elbow	9	0	1
16	F	II	TS	Forearm	5	0	0
17	M	IV	PUVA	Forehead	12	1	0
				Chin	12	1	0
18	F	V	None	Elbow	12	2	0

*Repigmentation: 0 = 0; 1 = 1-25%; 2 = 26-75%; 3 = 76-100%
**Erythema: 0 = none; 1 = mild; 2 = moderate; 3 = severe

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention. All patent applications, patents, patent publications and literature references cited in this specification are hereby incorporated by reference in their entirety.

What is claimed is:

1. A method of treating vitiligo consisting essentially of the steps of: (A) identifying an area of skin with an absence of melanin; and (B) repeatedly exposing said area of skin to laser light in the UVB range.

2. The method of claim **1**, wherein said laser light is generated by an excimer laser.

3. The method of claim **2**, wherein the wavelength of said laser light is 308 nm, and the intensity of said laser light is 60 mwatts.

4. The method of claim **1**, wherein the wavelength of said laser light is 290 to 320 nm.

5. The method of claim **1**, wherein each exposure of said area of skin to laser light occurs for an incrementally increased time period.

6. The method of claim **1** which comprises stimulating melanin production in said area of skin with said repeated exposures.

* * * * *

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(12) **United States Patent**
Spencer

(10) **Patent No.: US 7,261,729 B2**
(45) **Date of Patent: *Aug. 28, 2007**

(54) **TREATMENT OF VITILIGO**

(75) Inventor: **James M. Spencer**, St. Petersburg, FL (US)

(73) Assignee: **Mount Sinai School of Medicine**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: **Jul. 1, 2005**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 09/790,786, filed on Feb. 22, 2001, now Pat. No. 6,979,327.

(60) Provisional application No. 60/184,971, filed on Feb. 25, 2000.

(51) **Int. Cl.**
A61N 5/067 (2006.01)
A61B 18/20 (2006.01)

(52) **U.S. Cl.** **607/88**; 607/89; 607/94; 606/3; 606/9; 128/898

(58) **Field of Classification Search** 607/88–91, 607/94; 606/3, 9; 128/898
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,103,175	A		7/1978	Levin
4,558,700	A		12/1985	Mutzhas
4,674,507	A		6/1987	Basso
5,217,455	A		6/1993	Tan
5,312,395	A	*	5/1994	Tan et al. 606/9
5,433,942	A	*	7/1995	Wood et al. 424/59
6,017,360	A	*	1/2000	Chubb et al. 607/88
6,323,219	B1	*	11/2001	Costanzo 514/317
6,413,268	B1	*	7/2002	Hartman 607/94
6,436,127	B1	*	8/2002	Anderson et al. 607/89
6,979,327	B2	*	12/2005	Spencer 606/9
2003/0113540	A1	*	6/2003	Anderson et al. 428/403

OTHER PUBLICATIONS

Bossuyt et al., "the Development of Guidelines for the Treatment of Vitiligo," Arch Dermatol, vol. 135, Dec. 1999.*
Westerhof et al., "Treatment of Generalized Vitiligo in Children with Narrow-band (TL-01) UVB Radiation Therapy," J AM ACAD Dermatol, vol. 42, 2, pp. 245-253, Feb. 2000.*

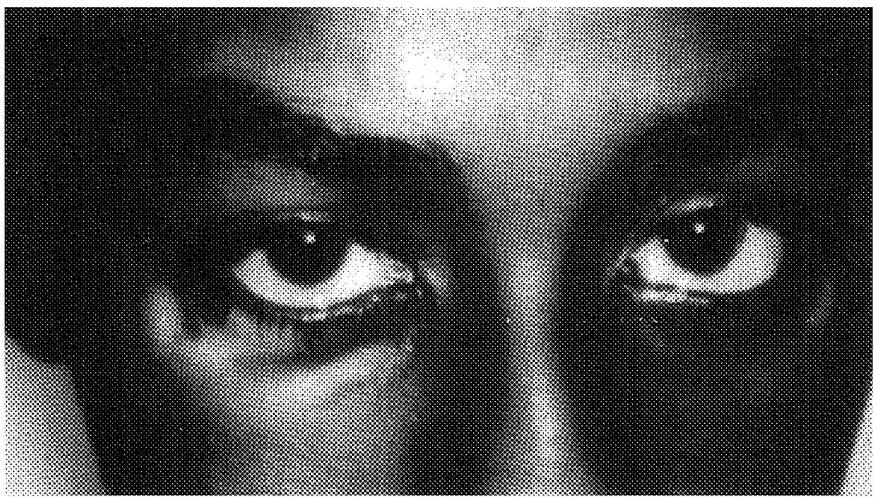
(Continued)

Primary Examiner—A. Farah
(74) *Attorney, Agent, or Firm*—Darby & Darby

(57) **ABSTRACT**

Disclosed herein is a novel method of treating vitiligo by using an excimer laser that emits light in the UVB range. The invention includes a method of incrementally increasing exposure of affected vitiligo areas with UVB laser light from an excimer laser to restore pigmentation to skin areas afflicted with vitiligo.

6 Claims, 7 Drawing Sheets
(6 of 7 Drawing Sheet(s) Filed in Color)



OTHER PUBLICATIONS

T.M. Lotti et al. "UV-B radiation microphototherapy. An elective treatment for segmental vitiligo." J Eur. Acad. Dermatol. Venereol. 13 (1999) 102-I 08.*

Lotti, T.M., Menchini G., Andreassi L. UV-B radiation microphototherapy. An elective treatment for segmental vitiligo. J. Eur. Acad. Dermatol Venereol; 1999, 13(2):102-8.

Asawanonda P., Anderson R., Chang Y., Taylor CR., "308-nm Excimer laser for the treatment of psoriasis" A dose response study, *Arch Dermatol* 2000; 136:619-624.

Elliott, J., "Clinical experiences with methosxalen in the treatment of vitiligo," *J. Invest Dermatol* (1959), 32:311-14.

Farah F., Kurban A., Chaglassian H., "The treatment of vitiligo with psoralens and triamcinolone by mouth," *Br J Bermatol* (1967), 79-89-91.

Njoo MD., Bos JD., Westerhof W., "Treatment of generalized vitiligo in children with narrow-band (TL-01) UVB radiation therapy," *J Am Acad Dermatol*, (2000), 42:245-53.

Njoo MD., Spuls PI., Bos JD., Westerhof W., et al., "Nonsurgical repigmentation therapies in vitiligo," *Arch Dermatol*, (1998), 134:1532-40.

Njoo MD., Westerhof W., Bos JD., Bossuyt PM., "The development of guidelines for the treatment of vitiligo," *Arch Dermatol*, (1999), 135, 1514-21.

Ohshiro T., "Laser treatment of vitiligo" *Amer Society of Leser Med. And Surgery Abstracts*, 123:98.

Ortonne J., "Psoralen therapy in vitiligo," *Clin Dermatol*, (1989), 7:120-35.

Preston DS., Stern RS., "Nonmelanoma cancers of the skin," *N Engl J Med*, (1992), 327:1649-62.

Sasaki K., Ohshiro T., "Role of low reactive-level laser therapy (LLLT) in the treatment of acquired and cicatrical vitiligo," *Laser Therapy*, (1989), 1:141-146.

Stern RS., Lang R., "Non-melanoma skin cancer occurring in patients treated with PUVA five to ten years after first treatment," *J Invest Dermatol*, (1988),91:120-4.

Thissen, M., MD and Westerhof, W., MD, "Laser Treatment for further depigmentation in vitiligo," *Pharmacology and Therapeutics*, (1997), 36: 386-3388.

Westerhof W., Nieuweboer-Krobotova L,. "Treatment of Vitiligo with UV-B radiation vs Topical psoralen plus UV-A," *Arch Dermatol* (1997), 133:1525-28.

Yu H., Wu M., Kao Y., Wu C., "Helium-neon laser treatment induces repigmentation in segmental-type vitiligo," *Journ of Invest Dermatol* Abstracts 526.

* cited by examiner

Figure. 1

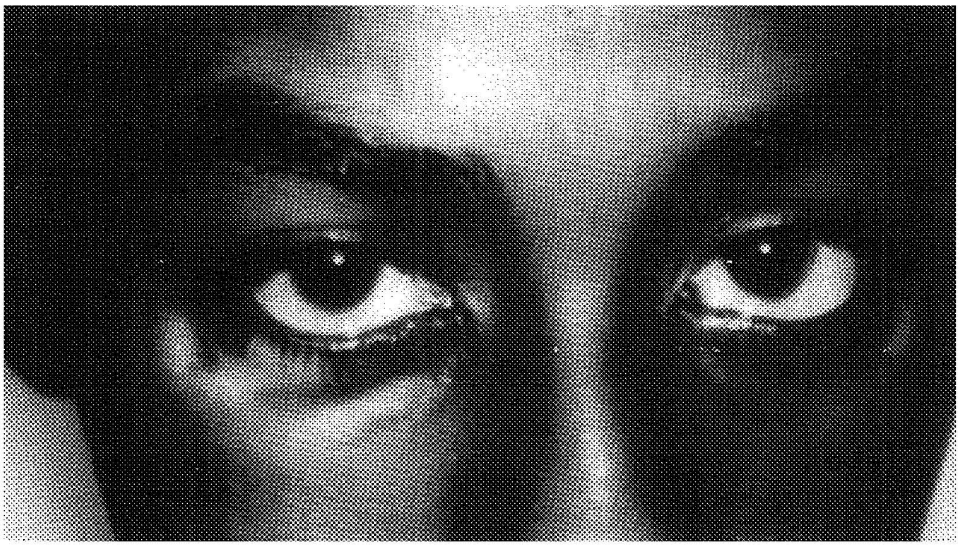


Figure. 2

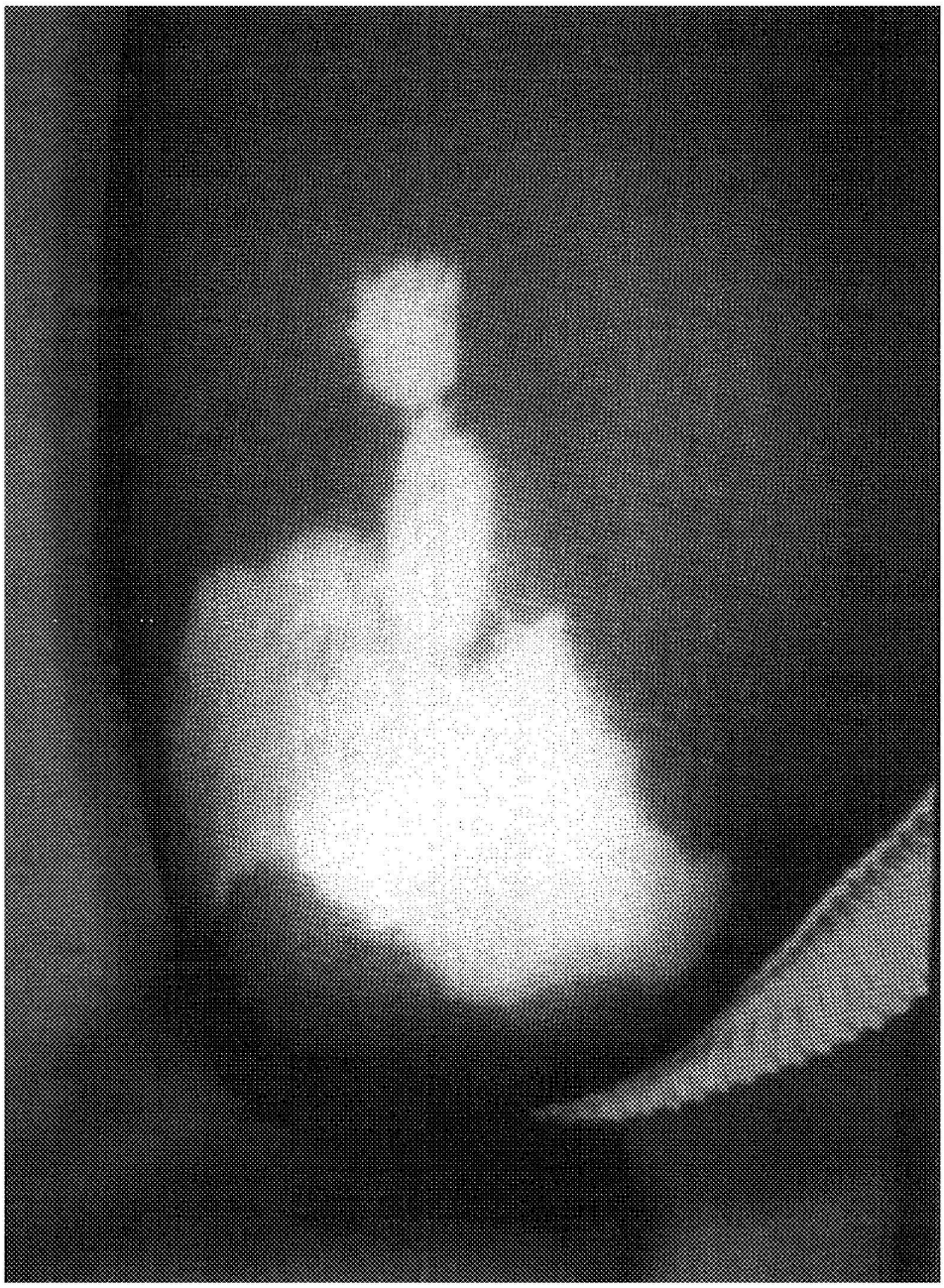
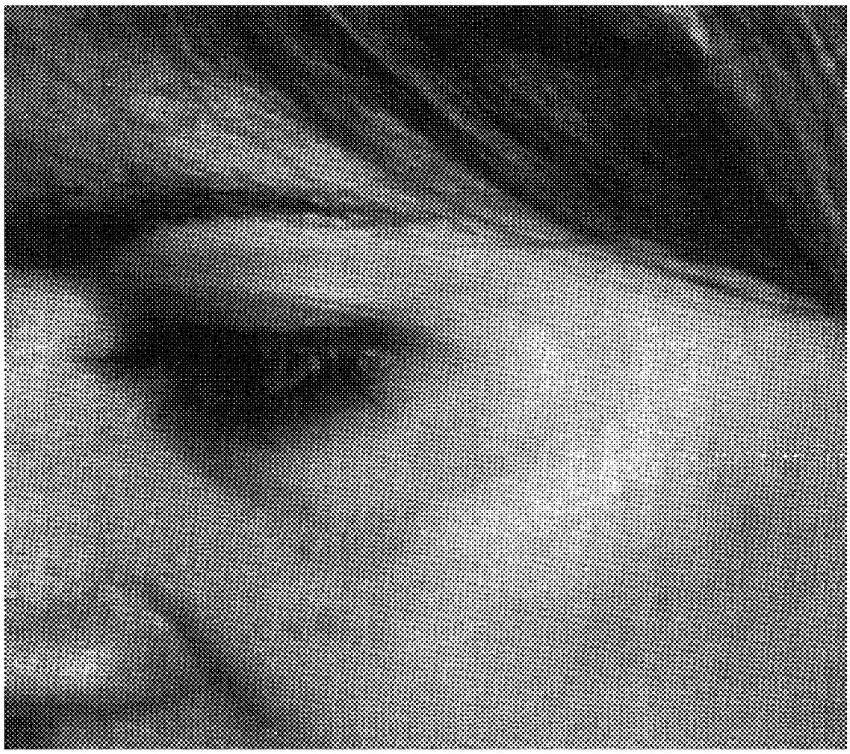
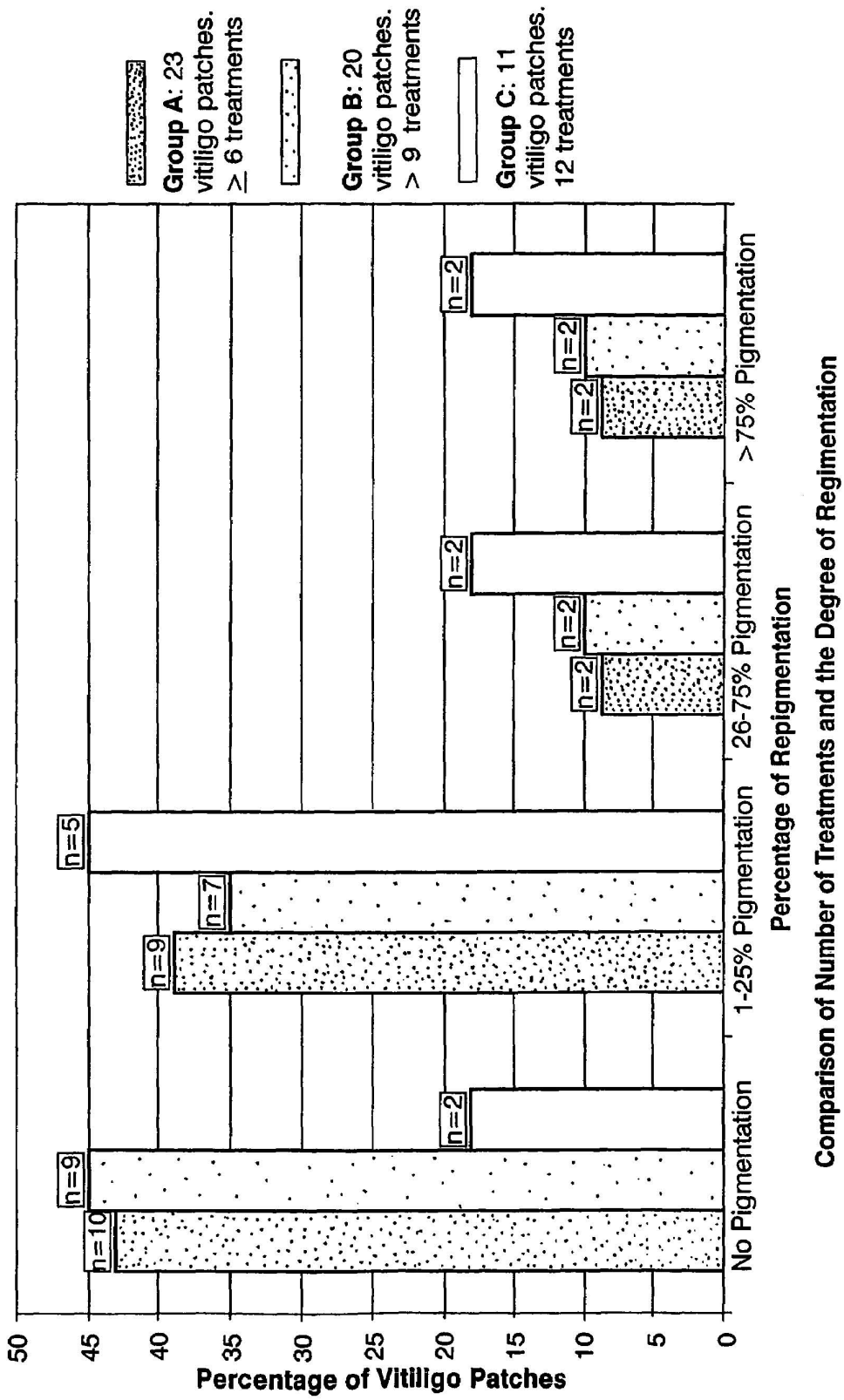


Figure. 3





Comparison of Number of Treatments and the Degree of Regimentation

Figure 4

Figure. 5

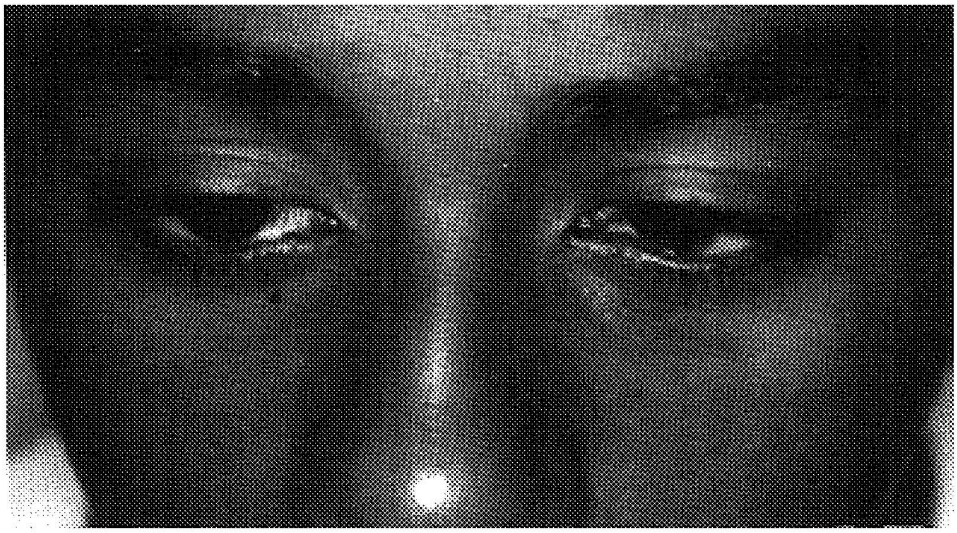


Figure. 6

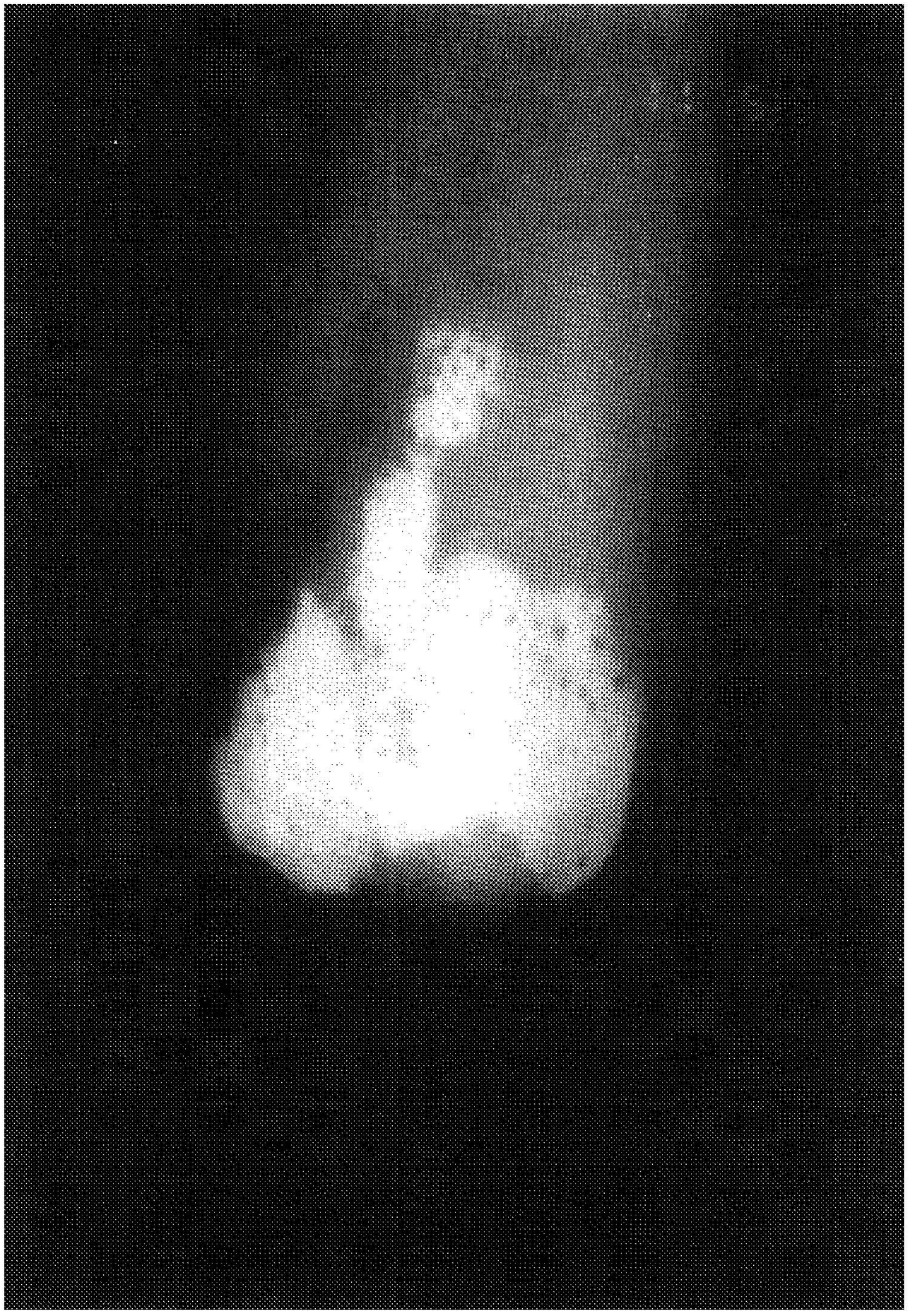


Figure. 7

TREATMENT OF VITILIGO

This application is a continuation of U.S. patent application Ser. No. 09/790,786, filed Feb. 22, 2001, now U.S. Pat. No. 6,979,327, which claims priority under 35 U.S.C. § 119 of Provisional Application Ser. No. 60/184,971 filed Feb. 25, 2000, incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

Vitiligo is a cutaneous disease in which there is a complete loss of pigment in localized areas of the skin. This loss of pigment results in the effected areas being completely white. This condition has a predilection for the skin around the mouth and the eyes. The result is cosmetically disfiguring, especially for dark skinned people. Furthermore, the depigmented skin is sun sensitive, and thus is subject to sunburns and skin cancer. In sum, vitiligo is both cosmetically and practically distressing to patients afflicted with the disease.

In normal skin, varying shades of brown are seen (depending on a person's race) representing the pigment melanin. This pigment is produced by a cell type known as a melanocyte. In vitiligo, there is an absence of melanocytes in the areas afflicted with the disorder. An absence of melanocytes results in an absence of melanin pigment, and thus the melanin-free area is white. Normal skin responds to ultraviolet light with an increase in the brown pigment melanin (tanning). Specifically, ultraviolet radiation stimulates melanocytes to proliferate and produce more melanin.

Attempts have also been made to "tan" vitiligo areas using ultraviolet light treatments. The ultraviolet spectrum is divided into two portions, "UVA" and "UVB," which is light of 320–400 nm and 290–320 nm in wavelength, respectively. UVB is much more effective at producing a tan in normal skin. In normal skin, melanocytes reside in the epidermis, which is the outer layer of the skin. The epidermis is only 0.1 mm thick, so the melanocytes are very near the surface. UVB radiation can only penetrate to about 0.1 mm, but this is sufficient to reach the melanocytes. In patients with vitiligo, these epidermal melanocytes are gone. In some cases, there are surviving melanocytes deeper in the skin down the hair follicles. These melanocytes may be several millimeters deep. UVB cannot penetrate this deep in the skin to stimulate these surviving deep melanocytes. Exposure to UVB results in a sunburn at the surface of the skin with no stimulation of these deep melanocytes. Thus attempts to repopulate the vitiligo areas with melanocytes deep in the skin in response to UVB exposure have failed. UVA will penetrate a bit deeper in the skin than UVB. However, UVA is very poor at stimulating melanocytes to proliferate and migrate.

DESCRIPTION OF RELATED ART

The present invention uses an excimer laser to restore pigmentation to skin areas afflicted with vitiligo, and is an improvement over current treatments for vitiligo. Currently, treatments for vitiligo suffer from a number of drawbacks. For instance, Fitzpatrick's Dermatology in General Medicine, Vol. 1, Chapter 89 (5th ed., I. M. Freedberg et al., eds., 1999) teaches the use of sunscreens and cosmetic cover-ups including dyes and conventional makeup as a way to mask skin areas afflicted with vitiligo. However, the ability of sunscreens to minimize contrast between normal skin and vitiligo-afflicted areas has been disappointing. Sunscreens, as well as cosmetics and dyes, are not permanent. These products tend to rub-off and have been of limited value in areas such as the lower neck, wrists and hands. In addition, unlike the present invention, sunscreens and cosmetics

cover-ups do not attempt to treat vitiligo, but simply blend in the affected areas with the surrounding skin. The prior art also teaches the use of topical glucocortoids to treat isolated areas of vitiligo. Fitzpatrick's Dermatology in General Medicine. However, the overall results tend to be disappointing. The present invention improves on these treatments by providing a more permanent restoration of pigmentation to vitiligo affected areas, with a relatively high rate of success.

Another known treatment for vitiligo attempts to increase the action of UVA light by combining exposure to UVA with a chemical that is applied to the skin to increase sensitivity to UVA. Fitzpatrick's Dermatology in General Medicine, Vol. 1, Chapter 89 (5th ed., I. M. Freedberg et al., eds., 1999). This chemical is known as psoralen, and psoralen and UVA together are known as PUVA. Specifically, high output UVA (320–400 nm) light bulbs are utilized within an indoor phototherapy unit. The patient applies psoralen to the effected areas, then stands inside the phototherapy unit for exposure to the UVA light emitted by conventional tube-style bulbs.

This type of PUVA treatment suffers from a number of drawbacks. Unlike the present invention, PUVA treatment is to the whole body, not just the vitiligo areas. Therefore PUVA therapy has been associated with the development of skin cancers. PUVA treatment is also time-consuming; a minimum of 100 treatments, given 2–3 times per week over many months, is necessary before any response is seen. In addition, this treatment has had a relatively low success rate. Significantly less than 50% of patients will respond to this treatment. The present invention, however, treats only those skin areas afflicted with vitiligo, and thus minimizes the risk of skin cancer. The present invention also is less time consuming, and enjoys a relatively higher success rate.

Topical PUVA also may be used to treat localized patches of vitiligo and consists of applying a topical preparation of 8-methoxypsoralen to the patch of vitiligo and exposing the patch to UVA radiation at intervals of two to three times weekly. This type of PUVA treatment also has a number of drawbacks. Erythema, blistering and hyperpigmentation of surrounding skin are common complications. In addition, the success rate is relatively low. Repigmentation is seen in only about half of treated patients. Westernof, W., et al., "Treatment of Vitiligo with UV-B Radiation vs. Topical Psoralen Plus UV-A," *Arch. Dermatol;* 1997; 133:1525–28.

Phototherapy with UV-A radiation and oral psoralens is another known treatment. UV-A irradiation occurs at intervals of two to three times weekly and is generally maintained for months to greater than a year. Once again, the success rate is relatively low. Elliott, J., "Clinical Experiences With Methosaxalen in the Treatment of Vitiligo", *J. Invest Dermatol;* 1959; 32: 311–314; Farah, F. et al, "The Treatment of Vitiligo with Psoralens and Triamcinolone By Mouth", *Br. J. Dermatol;* 1969; 79: 89–91; Ortonne J., "Psoralen Theraphy In Vitiligo", *Clin. Dermatol;* 1989; 7:120–135. Moreover, side effects of this type of PUVA include burning, nausea, erythema, lentigenes, pruritus, and cataracts.

UVB phototherapy is much more effective at stimulating melanocytes than PUVA. However, regular UVB light cannot penetrate the skin deeper than the epidermis, and hence is completely ineffective in stimulating the deep melanocytes underneath patches of vitiligo. The present invention overcomes this problem in the prior art through the use of an excimer laser which emits laser light in the ultraviolet range and provides higher energy fluences thereby decreasing the treatment time.

M. Thissen et al., Laser Treatment for Further Depigmentation in Vitiligo, International Journal of Dermatology, Vol. 36 (1997) teaches the use of a ruby laser to depigment

normal skin and bleach it to a white color. Ruby lasers, unlike excimer lasers, employ a ruby crystal to generate laser light in the red spectrum. The laser light is used to depigment normal skin, and does not attempt to restore or treat skin areas afflicted by vitiligo. Therefore, unlike the present invention which attempts to stimulate melanin production and restore pigmentation, patients subjected to the Thissen treatment end up depigmenting their remaining normal skin. The drawbacks of this treatment are that the depigmented skin lacks melanin and is the color white, which is generally less aesthetically desirable than the natural skin color of the patient. This depigmented skin is also more sensitive to the sun than normally pigmented skin, and the patient with depigmented skin must be protected from the sun for the rest of his or her life. Finally, the Thissen article acknowledges that this method is only effective in vitiligo afflicted patients where the skin has become over 80% depigmented.

K. Sasaki et al., Role of Low Reactive-Level Laser Therapy (LLLT) in the Treatment of Acquired and Cicatrical Vitiligo, Laser Therapy, Vol. 1 No. 3 (1989) teaches use of a diode laser, either alone or in combination with an argon laser, to revive dormant or malfunctioning melanocytes in order to repigment vitiligo afflicted skin areas. This technique suffers from the disadvantage that both the argon and diode lasers are needed in order to treat cicatrical-type vitiligo, or vitiligo that follows after scarring or trauma. Argon lasers also suffer from the disadvantage that they may cause thermal damage to the skin. In addition, argon lasers as disclosed in Sasaki emit visible light (488 nm and 514.5 nm), while diode lasers emit infrared light (830 nm). Unlike the present invention, these lasers do not emit UV light, and therefore do not benefit from the special ability UVB light has in stimulating melanocyte growth and melanin production.

H. Yu et al., Helium-Neon Laser Treatment Induces Repigmentation in Segmental-Type Vitiligo, Journal of Investigative Dermatology, Vol. 112(4) (1999) teaches use of a Helium-Neon laser that emits light in the visible red to infrared range, as opposed to UV light. Unlike the present invention, Helium-Neon laser light suffers from the disadvantage that it does not stimulate melanocytes directly, but instead induces nerve growth. For this reason, this method of treating vitiligo is confined to segmental-type vitiligo, which is vitiligo caused by dysfunction of nerves.

Lasers have also been used to treat vitiligo to aid in skin grafting. R. Kaufman, et al., Grafting of In Vitro Cultured Melanocytes onto Laser-Ablated Lesions in Vitiligo, ACTA Demato-Veneriologica, Vol. 78/2 (1998); J. S. Yang et al., Treatment of Vitiligo with Autologous Epidermal Grafting by Means of Pulsed Erbium: YAB Laser, Journal of the American Academy of Dermatology, Vol. 38/2 (1998). Unlike the present invention, these techniques are invasive and require that the vitiligo affected areas be relatively small and stable.

Narrowband UV-B phototherapy using a spectrum of 311–315 nm wavelength with a peak emission of 311 nm has been used to treat vitiligo. Westerhof et al. teaches the use of narrowband UV-B phototherapy at intervals of two times per week for four to twelve months. However, this method requires regular phototherapy sessions several times a week for up to a year to achieve a therapeutic response. UV-B phototherapy in general has few side effects and is mainly limited to erythema.

What is needed is a method of treating vitiligo with UVB light that treats only the areas of vitiligo with increased precision, at higher energy fluences, to reduce length of treatment. What is also needed is a method of treating vitiligo that is as effective as UVB light in stimulating melanocytes, but without the disadvantage of being unable to penetrate beyond the epidermal skin layer. What is also needed is a method of treating vitiligo that only treats the areas of the vitiligo, and not the entire body, to reduce the risk of skin cancers. Finally, what is needed is a method that restores pigmentation to skin areas afflicted with vitiligo, rather than simply covering the affected areas or bleaching normal skin white, so that the result is both more permanent and more aesthetically pleasing.

BRIEF SUMMARY OF THE INVENTION

The present invention is a method of treating vitiligo using an excimer laser, a laser which produces light in the UVB range. The present invention includes a method for treating vitiligo by incrementally increasing exposure of afflicted areas of skin with UVB laser light to restore the pigmentation in the areas afflicted with vitiligo. The present invention overcomes the problems associated with current vitiligo treatments through the use of an excimer laser. Laser light is coherent and collimated whereas regular light is incoherent and divergent, allowing laser UVB light to penetrate deeper into skin and quickly stimulate deep melanocytes underneath patches of vitiligo. Therefore unlike regular UVB light or, PUVA therapy, the present invention is able to better stimulate deep melanocytes, and is able to deliver higher energy fluences in less time than known treatments. Another advantage of the present invention is that laser treatment is confined to only those areas afflicted with vitiligo, not to normal skin, and thus significantly reduces risk of skin cancers over other types of therapy such as PUVA treatments. Yet another advantage of the present invention is that the vitiligo areas are treated and made darker, making the areas better match the natural skin color of the patient, as opposed to simply bleaching the surrounding non-vitiligo areas to an unnatural white. Finally, the present invention changes the actual pigment of the skin, and therefore will not rub or wash-off.

(A) BRIEF DESCRIPTION OF THE DRAWINGS

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

FIG. **1** depicts vitiligo involving periocular skin in an individual with phototype V skin before treatment.

FIG. **2** depicts vitiligo involving the extensor elbow in an individual with phototype V skin before treatment.

FIG. **3** depicts vitiligo involving the periocular skin in an individual with phototype III skin before treatment.

FIG. **4** depicts a comparison of the number of treatments and the degree of repigmentation in the study population.

FIG. **5** depicts complete repigmentation of the vitiligo-affected periocular skin shown in FIG. **1** after 5 treatments.

FIG. **6** depicts spotty follicular repigmentation of the vitiligo-affected extensor elbow shown in FIG. **2** after 12 treatments.

FIG. **7** depicts focal repigmentation of the vitiligo-affected periocular skin shown in FIG. **3** after 12 treatments.

(B) DETAILED DESCRIPTION OF THE INVENTION

The present invention is a method of using UVB laser light to treat vitiligo. Laser light is different than regular light in that it is coherent and collimated, which can be thought of as more "concentrated." A given dose of laser light is often much more effective in producing photochemical reactions than conventional light. Treatment of vitiligo with UVB laser light is superior because laser light 1)

penetrates deeper in the skin than conventional light, and 2) a given dose of light is delivered much more quickly with laser light. This second effect becomes important if stimulation of melanocytes has a time component, i.e. stimulation is more effective if done quickly.

Also claimed and disclosed is a method of using UVB laser light to treat vitiligo where the time of exposure to the vitiligo afflicted skin areas is gradually increased. A diagnosis of vitiligo is made clinically, and the absence of melanin is confirmed by Woods light examination. A Wood's light examination uses UV light, also known as "black light," to accentuate areas of white color. In the practicing invention, a patient afflicted with vitiligo is treated by exposing the afflicted area to the UVB laser beam at periodic intervals. For example, the exposure to the vitiligo afflicted skin areas can be administered between 1 to 5 times per week. The first treatment would last for up to 5 seconds, depending on the intensity setting of the laser beam. The greater the intensity, the shorter the exposure to the beam. The exposure time for each treatment would be gradually increased, to a maximum of 10 seconds.

In one embodiment of the invention, an excimer laser is used to generate the UVB laser light. An excimer laser is a laser which uses a rare-gas halide or rare-gas metal vapor and emits laser light in the ultraviolet (126 to 558 nm) range. Currently, only excimer lasers emit laser light in the UV range, although any future lasers that emit light in the UVB range would also be encompassed by this invention. The laser used should operate in a range between 290 and 320 nm in wavelength, the UVB range of light. The laser should be utilized at a setting of not more than 120 mwatts.

A 308 excimer laser from the Surgilight Corporation, Winter Park Fla., is preferred for use in practicing the present invention. This laser operates at 308 nm via a fiber optic cable with pulse duration of 120 nsec, fired at repetition rate of 20 hz. The laser spot size is 10×10 mm. A photometer measures laser output, and the laser is utilized at a setting of 60 mwatts. In one preferred method of treatment, a patient with vitiligo is exposed to the 308 nm excimer laser three times a week. The first treatment lasts 2 seconds. The patient returns, and if there is no sunburn, the treated area is retreated again for 2 seconds. If there is sunburn, treatment is withheld until the sunburn is gone. On the third visit, if there is no sunburn, the dose is increased to 4 seconds. This is repeated the fourth visit, and then increased to 6 seconds on the fifth visit. On the sixth visit, 6 seconds is given again. Therefore, in this preferred method, each dose is repeated once, then increased by two seconds, to a maximum of 10 seconds. Treatment is continued for one month, or until repigmentation occurs, which is a much shorter time than PUVA therapy, which typically takes 6 months before any result is seen. Repigmentation is the appearance of brown pigment in the treated area, and is documented by standardized photography. In preliminary trials, four out of five patients receiving treatment for a minimum of nine sessions showed some response. This is a significant and substantial improvement in success rate over PUVA, glucocortoids, or any other current therapy for vitiligo. The repigmented skin is also relatively more permanent than other treatments such as sunscreens and cosmetic cover-ups, and will not rub-off.

When compared to standard phototheraphy, the 308 nm excimer laser has the advantage of having increased precision and the ability to deliver higher energy fluences thereby decreasing treatment time.

EXAMPLES

The following are intended as non-limiting examples of the invention.

Six men and twelve women with multiple discreet chronic stable patches of vitiligo enrolled in the study. Most patients had received and failed a variety of prior therapies for vitiligo (Table 1). No patient received any additional vitiligo therapy for at least one month prior to and during the study.

Eighteen patients started the study with a total of twenty-nine treated vitiligo patches. All patients had untreated vitiligo patches that were used as controls. Test areas of vitiligo were treated using a 308-nm xenon chloride excimer laser. A 120-ns, 20-hz, pulse was used with a 10-mm by 10-mm spot size and a power output of 60 mw of laser light. Lesions were treated three times a week for a maximum of 12 treatments. Exposure time was started at 2 seconds and increased by 2 seconds at every other visit until complete repigmentation occurred or until the protocol (12 treatments) was completed. Treatment was withheld if sunburn was observed and held until resolution.

Treated areas were evaluated for repigmentation and erythema on separate four point scales. Repigmentation was graded on the percentage of treated area of repigmentation as follows: 0:0%, 1:1–25%, 2:26–75% and 3:76–100%. Sunburn (erythema) was similarly graded as follows: 0—None, 1—Mild, 2—Moderate, 3—Severe. Patients with no repigmentation were defined as non-responders.

Results

Twelve patients with 23 patches completed at least six treatments. Six patients with 11 patches of vitiligo completed all twelve treatments that required an average of four weeks to complete. Six patients dropped out of the study before completion of six treatments and resulted in one slight repigmentation and five non-responders. Two of the non-responders developed mild erythema. Twelve patients with six or more total treatments of 23 vitiligo patches resulted in partial repigmentation in 57% of twenty-three patches. Six patients who completed twelve treatments of 11 vitiligo patches resulted in partial repigmentation in 87% of eleven patches (FIG. **4**). There were no serious adverse events. Mild sunburn with persistent erythema lasting up to three weeks was observed in some patients. Patients with the most repigmentation were skin-types III–VI. Table 1 sets forth the results.

TABLE 1

Demographics and Study Results of Patients Involved In the Protocol

Patient	Sex	Skin Phototype	Prior Treatment	Treatment Locations	Treatments Received	% Repigmentation*	Erythema**
1	M	V	TS	Periocular	5	3	0
				Forearm	12	3	0
2	F	III	PUVA	Periocular	12	1	0
				Back	12	1	0
				Hand	12	0	0
				Thigh	12	1	0
3	F	I	None	L. Forearm	12	1	1
4	F	III–IV	None	L. Preauricular	9		

TABLE 1-continued

Demographics and Study Results of Patients Involved In the Protocol

Patient	Sex	Skin Phototype	Prior Treatment	Treatment Locations	Treatments Received	% Repigmentation*	Erythema**
5	M	II	None	L. Neck	3	0	1
6	F	II	TS. Folate	L. Hand	5	1	0
7	F	IV	PUVA	Finger	12	0	0
8	M	II	TS	Abdomen	3	0	1
9	F	VI	TS	R. Temple	2	0	0
10	F	II	None	R. Wrist	6		
11	F	III–IV	None	R. Axilla	8	1	1
				Sternum	8	1	1
12	F		None	R. Axilla	1	0	0
13	M	III–IV	None	Chin	10	0	1
				L. Elbow	10	0	1
				L. Arm	10	0	1
14	M	II	PUVA	L. periocular	10	0	1
				R. Elbow	10	1	0
				Chin	10	0	1
15	F	II	PUVA	L. Shin	9	1	0
				L. Elbow	9	0	1
16	F	II	TS	Forearm	5	0	0
17	M	IV	PUVA	Forehead	12	1	0
				Chin	12	1	0
18	F	V	None	Elbow	12	2	0

*Repigmentation: 0 = 0; 1 = 1–25%; 2 = 26–75%; 3 = 76–100%
**Erythema: 0 = none; 1 = mild; 2 = moderate; 3 = severe

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention. All patent applications, patents, patent publications and literature references cited in this specification are hereby incorporated by reference in their entirety.

What is claimed is:

1. A method of treating vitiligo comprising the steps of;

(A) identifying an area of skin with an absence of melanin, and

(B) repeatedly exposing said area of skin to laser light in the UVB range, wherein the intensity of said laser light is not more than 120 mwatts and the wavelength of said laser light is 290 to 320 nm.

2. A method of treating vitiligo comprising the steps of;

(A) identifying an area of skin with an absence of melanin, and

(B) repeatedly exposing said area of skin to laser light in the UVB range, wherein said area of skin is exposed 1–5 times a week, the laser light is generated by an excimer laser, the wavelength of said laser light is 308 nm, and the intensity of said laser light is 60 mwatts.

3. The method of claim **2** wherein said area of skin is exposed to said laser light for not more than 5 seconds during the first exposure, and the exposure time is then gradually increased to a maximum of 10 seconds per exposure.

4. A method of treating vitiligo comprising the steps of;

(A) identifying an area of skin with an absence of melanin, and

(B) repeatedly exposing said area of skin to laser light in the UVB range, wherein said area of skin is exposed at least 3 times a week, the laser light is generated by an excimer laser, the wavelength of said laser light is 308 nm, and the intensity of said laser light is 60 mwatts.

5. The method of claim **4** wherein said area of skin is exposed to said laser light for 2 seconds during the first exposure, and the exposure time then increased by 2 seconds after every two exposures.

6. A method of treating vitiligo comprising the steps of;

(A) identifying an area of skin with an absence of melanin, and

(B) repeatedly exposing said area of skin up to five times a week to laser light in the UVB range.

* * * * *

US006979327B2

(12) **United States Patent**
Spencer

(10) **Patent No.: US 6,979,327 B2**
(45) **Date of Patent: Dec. 27, 2005**

(54) **TREATMENT OF VITILIGO**

(75) Inventor: **James M. Spencer**, St. Petersburg, FL (US)

(73) Assignee: **Mount Sinai School of Medicine**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/790,786**

(22) Filed: **Feb. 22, 2001**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 60/184,971, filed on Feb. 25, 2000.

(51) **Int. Cl.**[7] **A61B 18/18**

(52) **U.S. Cl.** **606/9**; 606/3; 607/88; 607/89; 607/94; 128/898

(58) **Field of Search** 606/3, 9, 2; 607/88–91, 607/94; 128/898, 897

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,103,175	A		7/1978	Levin
4,558,700	A		12/1985	Mutzhas
4,674,507	A		6/1987	Basso
5,217,455	A		6/1993	Tan
5,312,395	A	*	5/1994	Tan et al. 606/9
5,433,942	A	*	7/1995	Wood et al. 424/59
6,017,360	A	*	1/2000	Chubb et al. 607/88
6,323,219	B1	*	11/2001	Costanzo 514/317
6,413,268	B1	*	7/2002	Hartman 607/94
6,436,127	B1	*	8/2002	Anderson et al. 607/89
2003/0113540	A1	*	6/2003	Anderson et al. 428/403

OTHER PUBLICATIONS

T.M. Lotti et al. "UV–B radiation microphototherapy. An elective treatment for segmental vitiligo." J Eur. Acad. Dermatol. Venereol. 13 (1999) 102–I 08.*

Bossuyt et al., "The Development of Guidelines for the Treatment of Vitiligo," Arch Dermatol, vol. 135, Dec. 1999.*

Westerhof et al., "Treatment of Generalized Vitiligo in Children with Narrow–band (TL–01) UVB Radiation Therapy,"J Am Acad Dermatol, vol. 42, 2, pp 245–253, Feb. 2000.*

Asawanonda P., Anderson R., Chang Y., Taylor CR., "308–nm Excimer laser for the treatment of psoriasis" A dose response study, *Arch Dermatol* 2000; 136:619–624.

Elliott, J., "Clinical experiences with methosxalen in the treatment of vitiligo," *J. invest Dermatol* (1959), 32:311–14.

Farah F., Kurban A., Chaglassian H., "The treatment of vitiligo with psoralens and triamcinolone by mouth," *Br J Bermatol* (1967), 79–89–91.

(Continued)

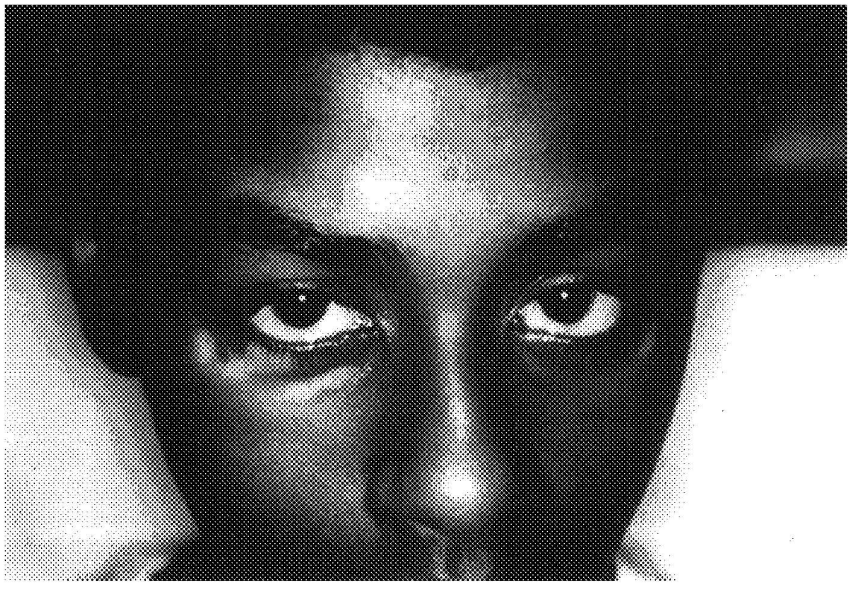
Primary Examiner—A. Farah
(74) *Attorney, Agent, or Firm*—Darby & Darby

(57) **ABSTRACT**

Disclosed herein is a novel method of treating vitiligo by using an excimer laser that emits light in the UVB range. The invention includes a method of incrementally increasing exposure of affected vitiligo areas with UVB laser light from an excimer laser to restore pigmentation to skin areas afflicted with vitiligo.

19 Claims, 7 Drawing Sheets

(6 of 7 Drawing Sheet(s) Filed in Color)



OTHER PUBLICATIONS

Njoo MD., Bos JD., Westerhof W., "Treatment of generalized vitiligo in children with narrow–band (TL–01) UVB radiation therapy," *J Am Acad Dermatol,* (2000), 42:245–53.

Mjoo MD., Spuls Pl., Bos JD., Westerhof W., et al., "Nonsurgical repigmentation therapies in vitiligo," *Arch Dermatol,* (1998), 134:1532–40.

Njoo MD., Westerhof W., Bos JD., Bossuyt PM., "The development of guidelines for the treatment of vitiligo," *Arch Dermatol,* (1999), 135, 1514–21.

Ohshiro T., "Laser treatment of vitiligo" *Amer Society of Laser Med. And Surgery Abstracts,* 123:98.

Ortonne J., "Psoralen therapy in vitiligo," *Clin Dermatol,* (1989), 7:120–35.

Preston DS., Stern RS., "Nonmelanoma cancers of the skin," *N Engl J Med,* (1992), 327:1649–62.

Sasaki K., Ohshiro T., "Role of low reactive–level laser therapy (LLLT) in the treatment of acquired and cicatrical vitiligo," *Laser Therapy,* (1989), 1:141–146.

Stern RS., Lang R., "Non–melanoma skin cancer occurring in patients treated with PUVA five to ten years after first treatment," *J Invest Dermatol,* (1988),91:120–4.

Thissen, M., MD and Westerhof, W., MD, "Laser Treatment for further depigmentation in vitiligo," *Pharmacology and Therapeutics,* (1997), 36: 386–3388.

Westerhof W., Nieuweboer–Krobotova L,. "Treatment of Vitiligo with UV–B radiation vs Topical psoralen plus UV–A," *Arch Dermatol* (1997), 133:1525–28.

Yu H., Wu M., Kao Y., Wu C., "Helium–neon laser treatment induces repigmentation in segmental–type vitiligo," *Journ of Invest Dermatol* Abstracts 526.

Lotti, T.M., Menchini G., Andreassi L. UV–B radiation microphototherapy. An elective treatment for segmental vitiligo. J. Eur. Acad. Dermatol Venereol; 1999, 13(2):102–8.

Elliott J., "Clinical Experiences With Methosxalen In The Treatment Of Vitiligo", *J. Invest Dermatol.,* 1959; 32:311–14.

Farah F. et al., "The Treatment Of Vitiligo With Psoralens and Triamcinolone By Mouth", *Br. J. Dermatol.,* 1967; 79:89–91.

Ortonne J., "Psoralen Therapy In Vitiligo", *Clin. Dermatol.,* 1989; 7:120–35.

Stern, R.S. et al., "Non–melanoma Skin Cancer Occurring In Patients Treated With PUVA Five To Ten Years After First Treatment"; *J. Invest. Dermatol.,* 1988; 91:120–4.

Preston, D.S. et al., "Nonmelanoma Cancers Of The Skin", *N Engl. J. Med.,* 1992; 327:1649–62.

Westerhof W. et al., "Treatment Of Vitiligo With UV–B Radiation vs. Topical Psoralen Plus UV–A", *Arch Dermatol,* 1997; 133:1525–28.

Njoo, M.D. et al., "Treatment Of Generalized Vitiligo In Children With Narrow–Band (TL–01) UVB Radiation Therapy"; *J. Am. Acad. Dermatol.,* 2000; 42:245–53.

Njoo, M.D. et al., "Nonsurgical Repigmentation Therapies In Vitiligo", *Arch Dermatol.,* 1998; 134:1532–40.

Asawanonda, P. et al., "308–nm Excimer Laser For The Treatment of Psoriasis. A Dose Response Study", *Arch Dermatol.* 2000; 136:619–624.

Njoo, M.D. et al., "The Development Of Guidelines For The Treatment Of Vitiligo", *Arch Dermatol.* , 1999; 135:1514–21.

* cited by examiner

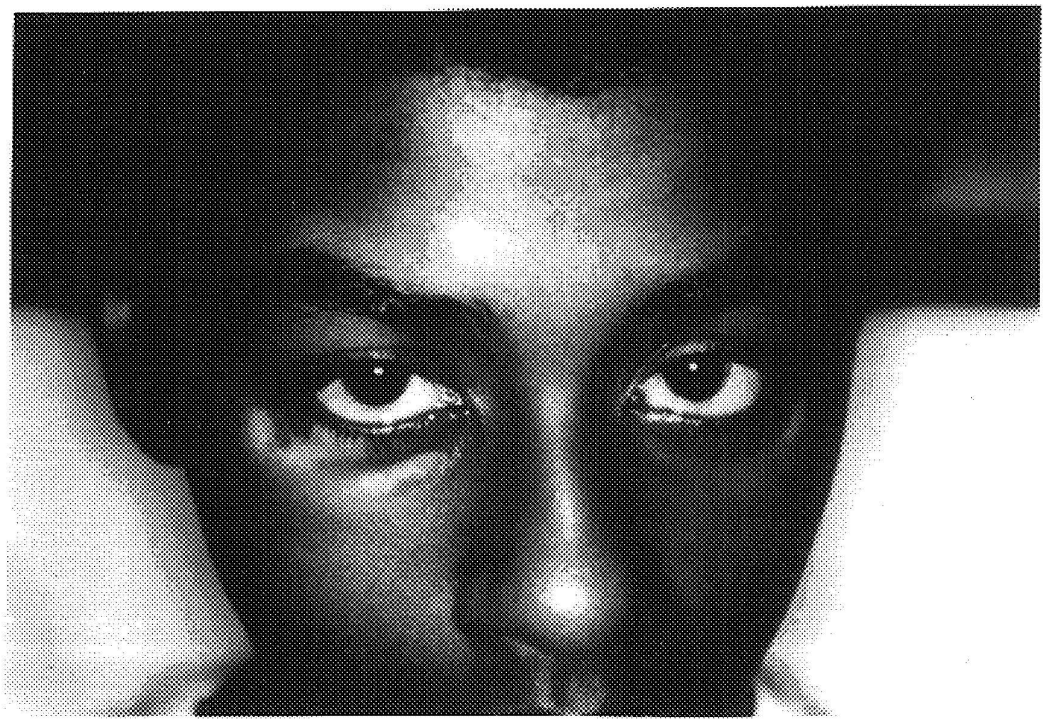


Figure 1

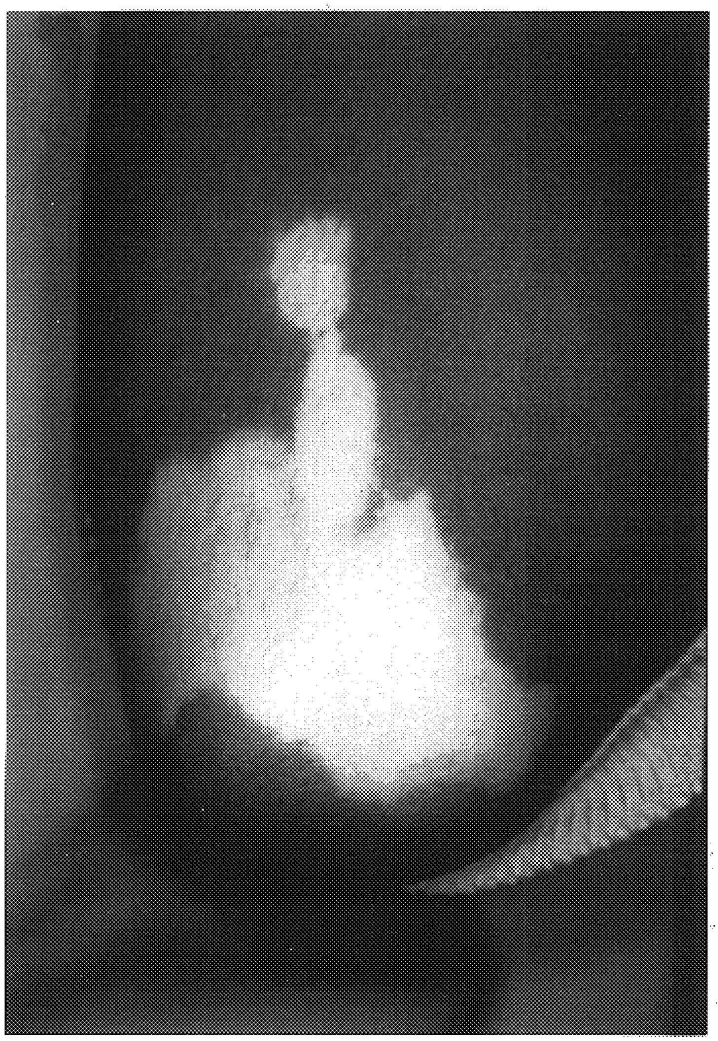


Figure 2

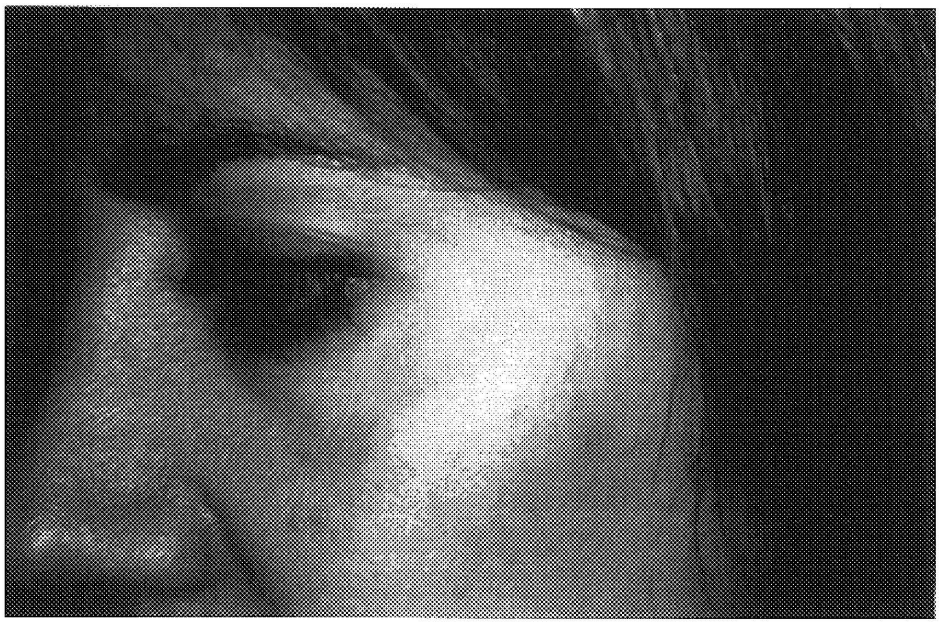
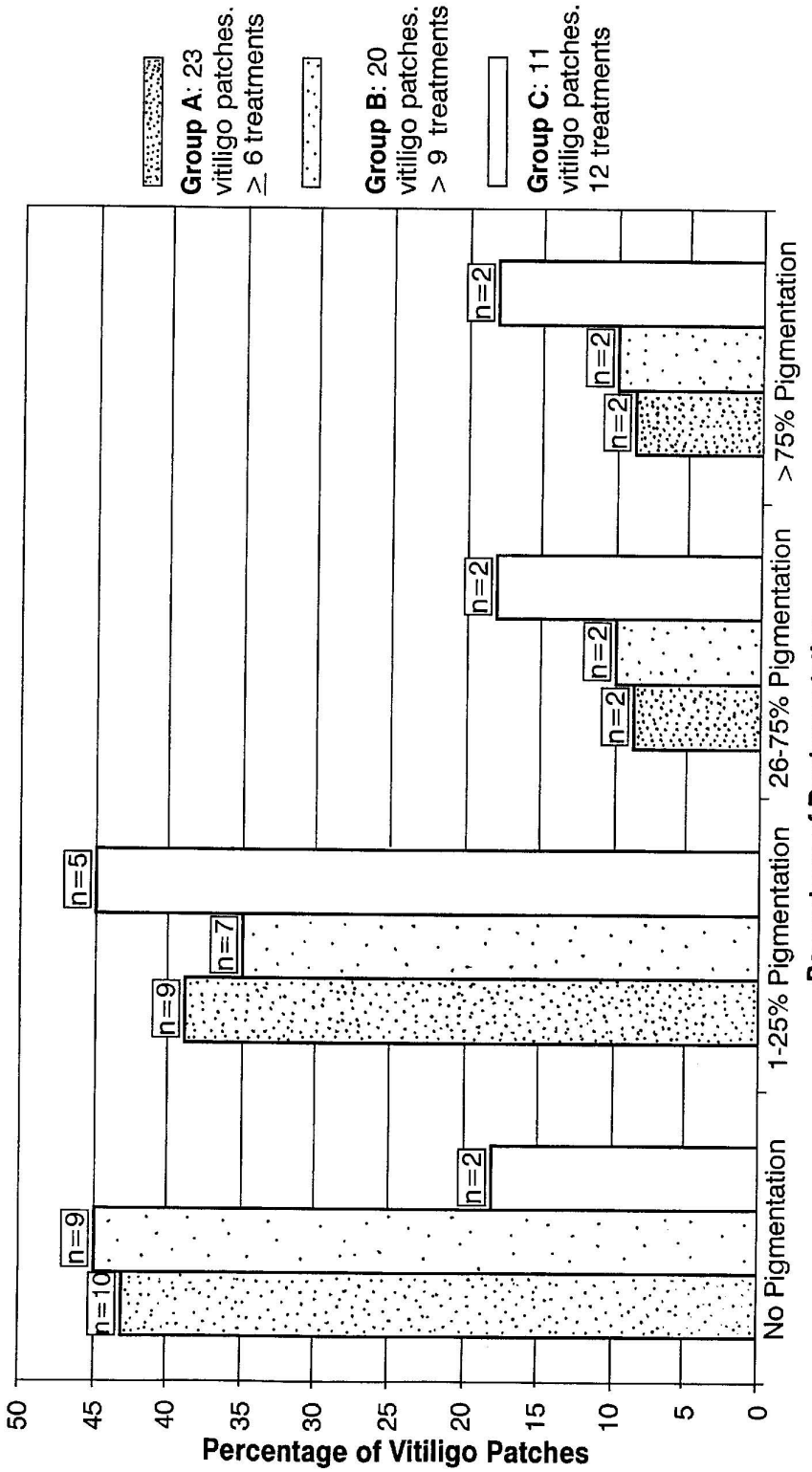


Figure 3



Comparison of Number of Treatments and the Degree of Regimentation

Figure 4

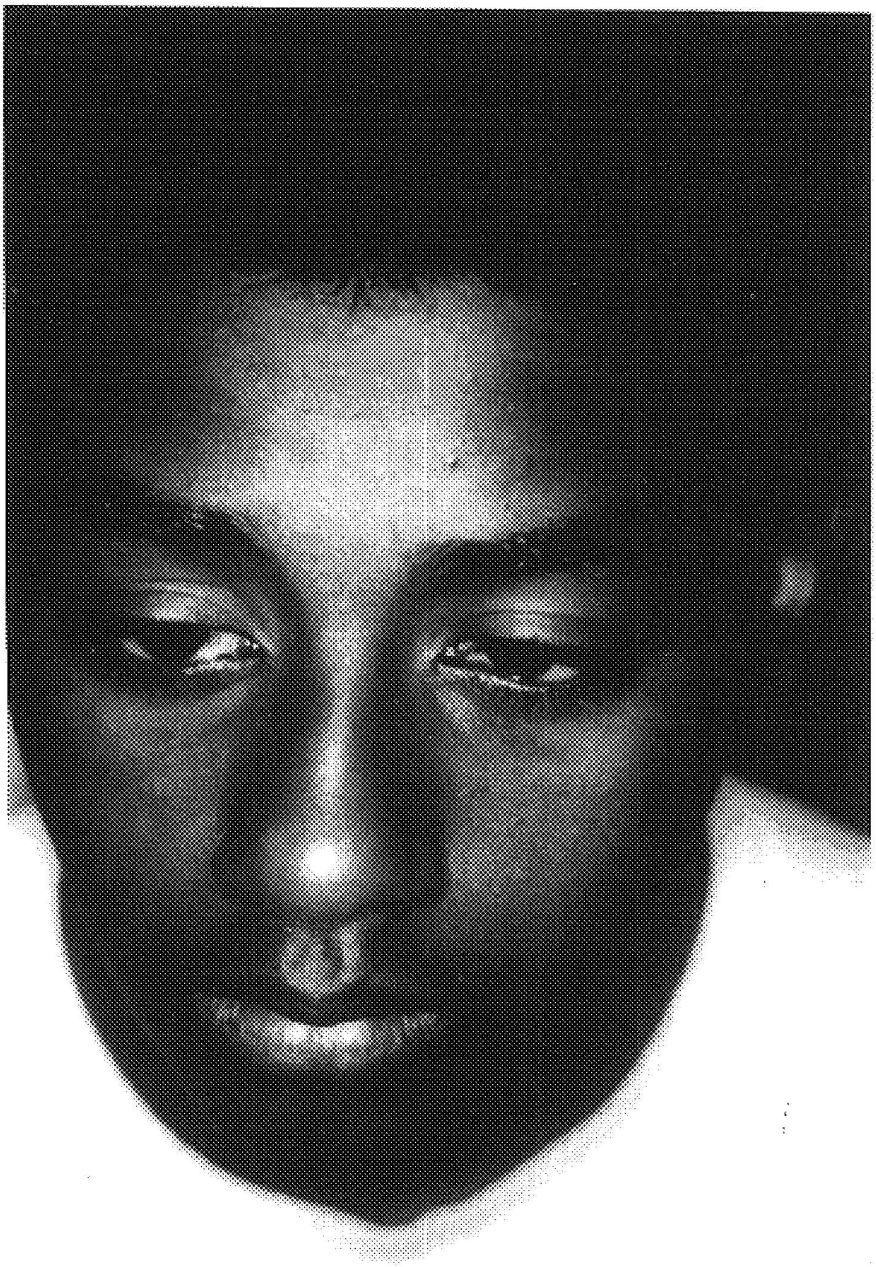


Figure 5

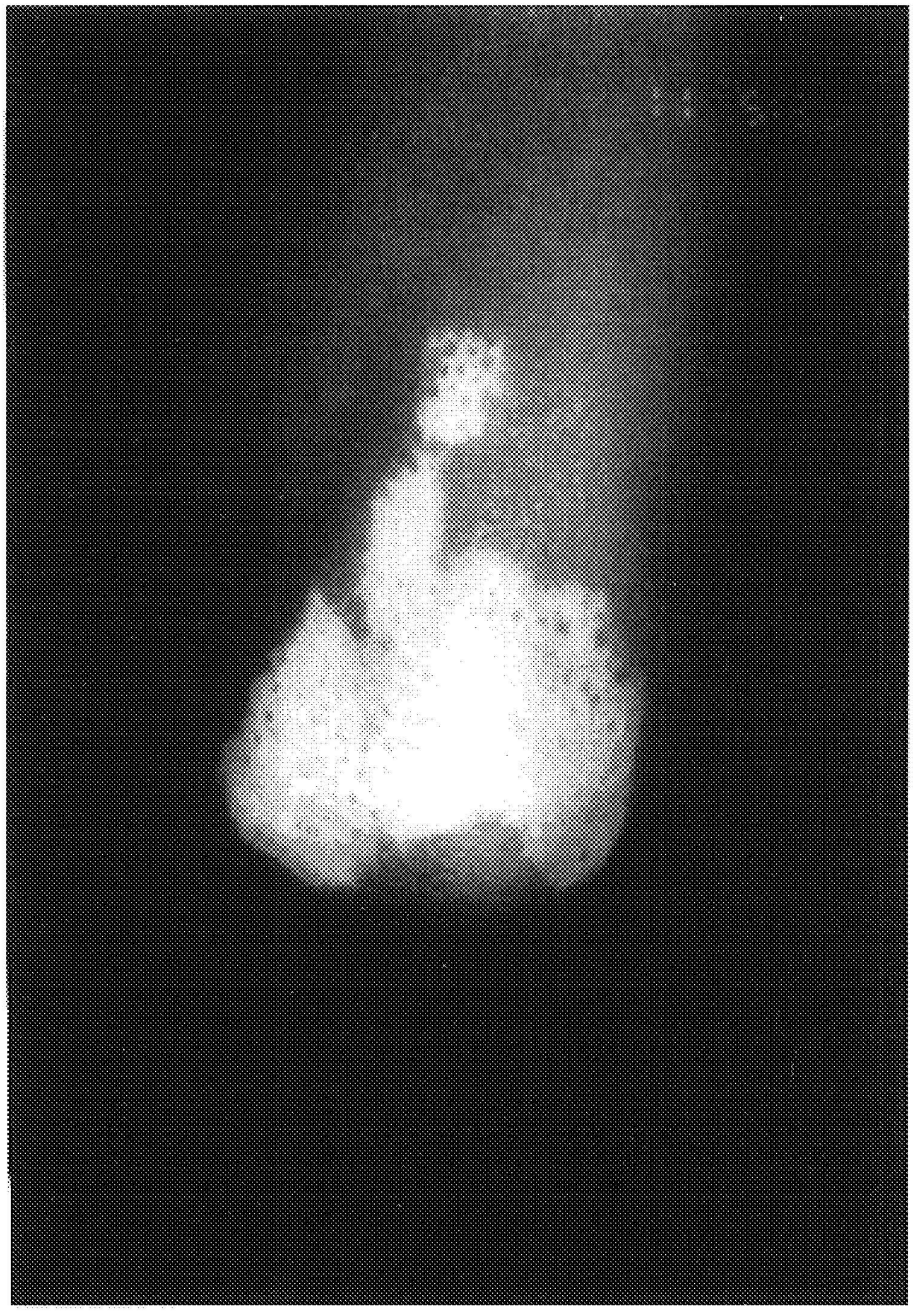


Figure 6

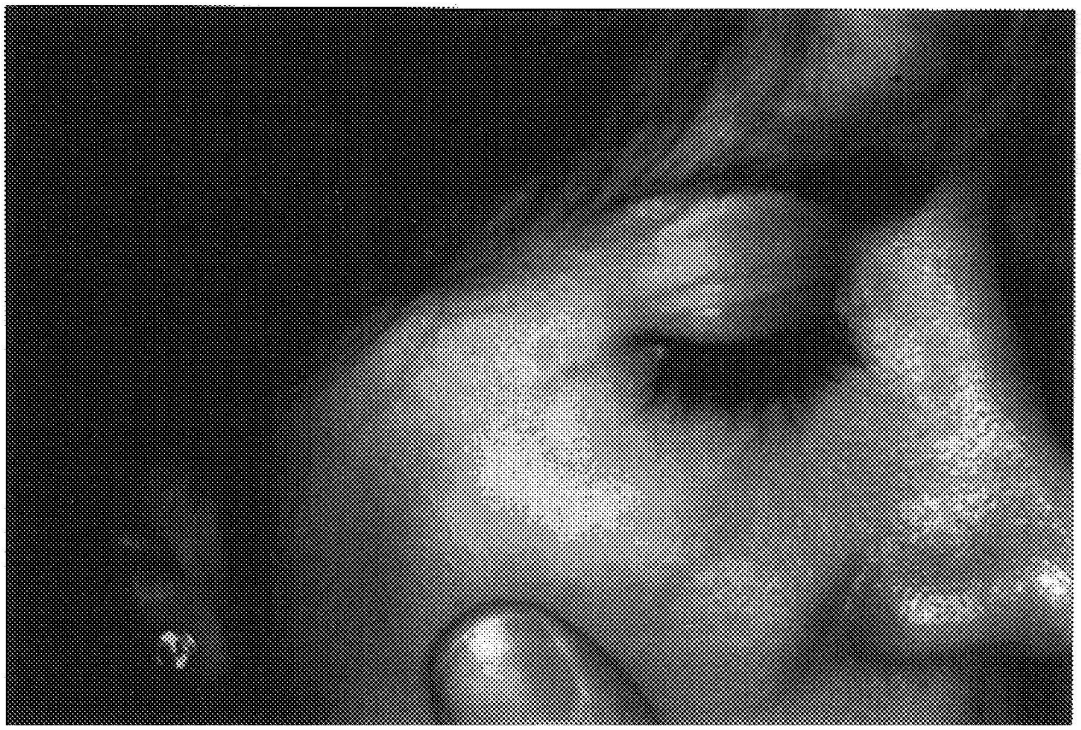


Figure 7

TREATMENT OF VITILIGO

This application claims priority under 35 U.S.C. § 119 from the Provisional Application Ser. No. 60/184,971 filed Feb. 25, 2000, incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

Vitiligo is a cutaneous disease in which there is a complete loss of pigment in localized areas of the skin. This loss of pigment results in the effected areas being completely white. This condition has a predilection for the skin around the mouth and the eyes. The result is cosmetically disfiguring, especially for dark skinned people. Furthermore, the depigmented skin is sun sensitive, and thus is subject to sunburns and skin cancer. In sum, vitiligo is both cosmetically and practically distressing to patients afflicted with the disease.

In normal skin, varying shades of brown are seen (depending on a person's race) representing the pigment melanin. This pigment is produced by a cell type known as a melanocyte. In vitiligo, there is an absence of melanocytes in the areas afflicted with the disorder. An absence of melanocytes results in an absence of melanin pigment, and thus the melanin-free area is white. Normal skin responds to ultraviolet light with an increase in the brown pigment melanin (tanning). Specifically, ultraviolet radiation stimulates melanocytes to proliferate and produce more melanin.

Attempts have also been made to "tan" vitiligo areas using ultraviolet light treatments. The ultraviolet spectrum is divided into two portions, "UVA" and "UVB," which is light of 320–400 nm and 290–320 nm in wavelength, respectively. UVB is much more effective at producing a tan in normal skin. In normal skin, melanocytes reside in the epidermis, which is the outer layer of the skin. The epidermis is only 0.1 mm thick, so the melanocytes are very near the surface. UVB radiation can only penetrate to about 0.1 mm, but this is sufficient to reach the melanocytes. In patients with vitiligo, these epidermal melanocytes are gone. In some cases, there are surviving melanocytes deeper in the skin down the hair follicles. These melanocytes may be several millimeters deep. UVB cannot penetrate this deep in the skin to stimulate these surviving deep melanocytes. Exposure to UVB results in a sunburn at the surface of the skin with no stimulation of these deep melanocytes. Thus attempts to repopulate the vitiligo areas with melanocytes deep in the skin in response to UVB exposure have failed. UVA will penetrate a bit deeper in the skin than UVB. However, UVA is very poor at stimulating melanocytes to proliferate and migrate.

DESCRIPTION OF RELATED ART

The present invention uses an excimer laser to restore pigmentation to skin areas afflicted with vitiligo, and is an improvement over current treatments for vitiligo. Currently, treatments for vitiligo suffer from a number of drawbacks. For instance, Fitzpatrick's Dermatology in General Medicine, Vol. 1, Chapter 89 (5^{th} ed., I. M. Freedberg et al., eds., 1999) teaches the use of sunscreens and cosmetic cover-ups including dyes and conventional makeup as a way to mask skin areas afflicted with vitiligo. However, the ability of sunscreens to minimize contrast between normal skin and vitiligo-afflicted areas has been disappointing. Sunscreens, as well as cosmetics and dyes, are not permanent. These products tend to rub-off and have been of limited value in areas such as the lower neck, wrists and hands. In addition, unlike the present invention, sunscreens and cosmetics cover-ups do not attempt to treat vitiligo, but simply blend in the affected areas with the surrounding skin. The prior art also teaches the use of topical glucocortoids to treat isolated areas of vitiligo. Fitzpatrick's Dermatology in General Medicine. However, the overall results tend to be disappointing. The present invention improves on these treatments by providing a more permanent restoration of pigmentation to vitiligo affected areas, with a relatively high rate of success.

Another known treatment for vitiligo attempts to increase the action of UVA light by combining exposure to UVA with a chemical that is applied to the skin to increase sensitivity to UVA. Fitzpatrick's Dermatology in General Medicine, Vol. 1, Chapter 89 (5^{th} ed., I. M. Freedberg et al., eds., 1999). This chemical is known as psoralen, and psoralen and UVA together are known as PUVA. Specifically, high output UVA (320–400 nm) light bulbs are utilized within an indoor phototherapy unit. The patient applies psoralen to the effected areas, then stands inside the phototherapy unit for exposure to the UVA light emitted by conventional tube-style bulbs.

This type of PUVA treatment suffers from a number of drawbacks. Unlike the present invention, PUVA treatment is to the whole body, not just the vitiligo areas. Therefore PUVA therapy has been associated with the development of skin cancers. PUVA treatment is also time-consuming; a minimum of 100 treatments, given 2–3 times per week over many months, is necessary before any response is seen. In addition, this treatment has had a relatively low success rate. Significantly less than 50% of patients will respond to this treatment. The present invention, however, treats only those skin areas afflicted with vitiligo, and thus minimizes the risk of skin cancer. The present invention also is less time consuming, and enjoys a relatively higher success rate.

Topical PUVA also may be used to treat localized patches of vitiligo and consists of applying a topical preparation of 8-methoxypsoralen to the patch of vitiligo and exposing the patch to UVA radiation at intervals of two to three times weekly. This type of PUVA treatment also has a number of drawbacks. Erythema, blistering and hyperpigmentation of surrounding skin are common complications. In addition, the success rate is relatively low. Repigmentation is seen in only about half of treated patients. Westernof, W., et al., "Treatment of Vitiligo with UV-B Radiation vs. Topical Psoralen Plus UV-A," *Arch. Dermatol;* 1997; 133:1525–28.

Phototherapy with UV-A radiation and oral psoralens is another known treatment. UV-A irradiation occurs at intervals of two to three times weekly and is generally maintained for months to greater than a year. Once again, the success rate is relatively low. Elliott, J., "Clinical Experiences With Methosaxalen in the Treatment of Vitiligo", *J. Invest Dermatol;* 1959; 32: 311–314; Farah, F. et al, "The Treatment of Vitiligo with Psoralens and Triamcinolone By Mouth", *Br. J. Dermatol;* 1969; 79: 89–91; Ortonne J., "Psoralen Theraphy In Vitiligo", *Clin. Dermatol;* 1989; 7:120–135. Moreover, side effects of this type of PUVA include burning, nausea, erythema, lentigenes, pruritus, and cataracts.

UVB phototherapy is much more effective at stimulating melanocytes than PUVA. However, regular UVB light cannot penetrate the skin deeper than the epidermis, and hence is completely ineffective in stimulating the deep melanocytes underneath patches of vitiligo. The present invention overcomes this problem in the prior art through the use of an excimer laser which emits laser light in the ultraviolet range

and provides higher energy fluences thereby decreasing the treatment time.

M. Thissen et al., Laser Treatment for Further Depigmentation in Vitiligo, International Journal of Dermatology, Vol. 36 (1997) teaches the use of a ruby laser to depigment normal skin and bleach it to a white color. Ruby lasers, unlike excimer lasers, employ a ruby crystal to generate laser light in the red spectrum. The laser light is used to depigment normal skin, and does not attempt to restore or treat skin areas afflicted by vitiligo. Therefore, unlike the present invention which attempts to stimulate melanin production and restore pigmentation, patients subjected to the Thissen treatment end up depigmenting their remaining normal skin. The drawbacks of this treatment are that the depigmented skin lacks melanin and is the color white, which is generally less aesthetically desirable than the natural skin color of the patient. This depigmented skin is also more sensitive to the sun than normally pigmented skin, and the patient with depigmented skin must be protected from the sun for the rest of his or her life. Finally, the Thissen article acknowledges that this method is only effective in vitiligo afflicted patients where the skin has become over 80% depigmented.

K. Sasaki et al., Role of Low Reactive-Level Laser Therapy (LLLT) in the Treatment of Acquired and Cicatrical Vitiligo, Laser Therapy, Vol. 1 No. 3 (1989) teaches use of a diode laser, either alone or in combination with an argon laser, to revive dormant or malfunctioning melanocytes in order to repigment vitiligo afflicted skin areas. This technique suffers from the disadvantage that both the argon and diode lasers are needed in order to treat cicatrical-type vitiligo, or vitiligo that follows after scarring or trauma. Argon lasers also suffer from the disadvantage that they may cause thermal damage to the skin. In addition, argon lasers as disclosed in Sasaki emit visible light (488 nm and 514.5 nm), while diode lasers emit infrared light (830 nm). Unlike the present invention, these lasers do not emit UV light, and therefore do not benefit from the special ability UVB light has in stimulating melanocyte growth and melanin production.

H. Yu et al., Helium-Neon Laser Treatment Induces Repigmentation in Segmental-Type Vitiligo, Journal of Investigative Dermatology, Vol. 112(4) (1999) teaches use of a Helium-Neon laser that emits light in the visible red to infrared range, as opposed to UV light. Unlike the present invention, Helium-Neon laser light suffers from the disadvantage that it does not stimulate melanocytes directly, but instead induces nerve growth. For this reason, this method of treating vitiligo is confined to segmental-type vitiligo, which is vitiligo caused by dysfunction of nerves.

Lasers have also been used to treat vitiligo to aid in skin grafting. R. Kaufman, et al., Grafting of In Vitro Cultured Melanocytes onto Laser-Ablated Lesions in Vitiligo, ACTA Demato-Veneriologica, Vol. 78/2 (1998); J. S. Yang et al., Treatment of Vitiligo with Autologous Epidermal Grafting by Means of Pulsed Erbium:YAB Laser, Journal of the American Academy of Dermatology, Vol. 38/2 (1998). Unlike the present invention, these techniques are invasive and require that the vitiligo affected areas be relatively small and stable.

Narrowband UV-B phototherapy using a spectrum of 311–315 nm wavelength with a peak emission of 311 nm has been used to treat vitiligo. Westerhof et al. teaches the use of narrowband UV-B phototherapy at intervals of two times per week for four to twelve months. However, this method requires regular phototherapy sessions several times a week for up to a year to achieve a therapeutic response. UV-B phototherapy in general has few side effects and is mainly limited to erythema.

What is needed is a method of treating vitiligo with UVB light that treats only the areas of vitiligo with increased precision, at higher energy fluences, to reduce length of treatment. What is also needed is a method of treating vitiligo that is as effective as UVB light in stimulating melanocytes, but without the disadvantage of being unable to penetrate beyond the epidermal skin layer. What is also needed is a method of treating vitiligo that only treats the areas of the vitiligo, and not the entire body, to reduce the risk of skin cancers. Finally, what is needed is a method that restores pigmentation to skin areas afflicted with vitiligo, rather than simply covering the affected areas or bleaching normal skin white, so that the result is both more permanent and more aesthetically pleasing.

BRIEF SUMMARY OF THE INVENTION

The present invention is a method of treating vitiligo using an excimer laser, a laser which produces light in the UVB range. The present invention includes a method for treating vitiligo by incrementally increasing exposure of afflicted areas of skin with UVB laser light to restore the pigmentation in the areas afflicted with vitiligo. The present invention overcomes the problems associated with current vitiligo treatments through the use of an excimer laser. Laser light is coherent and collimated whereas regular light is incoherent and divergent, allowing laser UVB light to penetrate deeper into skin and quickly stimulate deep melanocytes underneath patches of vitiligo. Therefore unlike regular UVB light or, PUVA therapy, the present invention is able to better stimulate deep melanocytes, and is able to deliver higher energy fluences in less time than known treatments. Another advantage of the present invention is that laser treatment is confined to only those areas afflicted with vitiligo, not to normal skin, and thus significantly reduces risk of skin cancers over other types of therapy such as PUVA treatments. Yet another advantage of the present invention is that the vitiligo areas are treated and made darker, making the areas better match the natural skin color of the patient, as opposed to simply bleaching the surrounding non-vitiligo areas to an unnatural white. Finally, the present invention changes the actual pigment of the skin, and therefore will not rub or wash-off.

(A) BRIEF DESCRIPTION OF THE DRAWINGS

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

FIG. **1** depicts vitiligo involving periocular skin in an individual with phototype V skin before treatment.

FIG. **2** depicts vitiligo involving the extensor elbow in an individual with phototype V skin before treatment.

FIG. **3** depicts vitiligo involving the periocular skin in an individual with phototype III skin before treatment.

FIG. **4** depicts a comparison of the number of treatments and the degree of repigmentation in the study population.

FIG. **5** depicts complete repigmentation of the vitiligo-affected periocular skin shown in FIG. **1** after 5 treatments.

FIG. **6** depicts spotty follicular repigmentation of the vitiligo-affected extensor elbow shown in FIG. **2** after 12 treatments.

FIG. **7** depicts focal repigmentation of the vitiligo-affected periocular skin shown in FIG. **3** after 12 treatments.

(B) DETAILED DESCRIPTION OF THE INVENTION

The present invention is a method of using UVB laser light to treat vitiligo. Laser light is different than regular light in that it is coherent and collimated, which can be thought of as more "concentrated." A given dose of laser light is often much more effective in producing photochemical reactions than conventional light. Treatment of vitiligo with UVB laser light is superior because laser light 1) penetrates deeper in the skin than conventional light, and 2) a given dose of light is delivered much more quickly with laser light. This second effect becomes important if stimulation of melanocytes has a time component, i.e. stimulation is more effective if done quickly.

Also claimed and disclosed is a method of using UVB laser light to treat vitiligo where the time of exposure to the vitiligo afflicted skin areas is gradually increased. A diagnosis of vitiligo is made clinically, and the absence of melanin is confirmed by Woods light examination. A Wood's light examination uses UV light, also known as "black light," to accentuate areas of white color. In the practicing invention, a patient afflicted with vitiligo is treated by exposing the afflicted area to the UVB laser beam at periodic intervals. For example, the exposure to the vitiligo afflicted skin areas can be administered between 1 to 5 times per week. The first treatment would last for up to 5 seconds, depending on the intensity setting of the laser beam. The greater the intensity, the shorter the exposure to the beam. The exposure time for each treatment would be gradually increased, to a maximum of 10 seconds.

In one embodiment of the invention, an excimer laser is used to generate the UVB laser light. An excimer laser is a laser which uses a rare-gas halide or rare-gas metal vapor and emits laser light in the ultraviolet (126 to 558 nm) range. Currently, only excimer lasers emit laser light in the UV range, although any future lasers that emit light in the UVB range would also be encompassed by this invention. The laser used should operate in a range between 290 and 320 nm in wavelength, the UVB range of light. The laser should be utilized at a setting of not more than 120 mwatts.

A 308 excimer laser from the Surgilight Corporation, Winter Park Fla., is preferred for use in practicing the present invention. This laser operates at 308 nm via a fiber optic cable with pulse duration of 120 nsec, fired at repetition rate of 20 hz. The laser spot size is 10×10 mm. A photometer measures laser output, and the laser is utilized at a setting of 60 mwatts. In one preferred method of treatment, a patient with vitiligo is exposed to the 308 nm excimer laser three times a week. The first treatment lasts 2 seconds. The patient returns, and if there is no sunburn, the treated area is retreated again for 2 seconds. If there is sunburn, treatment is withheld until the sunburn is gone. On the third visit, if there is no sunburn, the dose is increased to 4 seconds. This is repeated the fourth visit, and then increased to 6 seconds on the fifth visit. On the sixth visit, 6 seconds is given again. Therefore, in this preferred method, each dose is repeated once, then increased by two seconds, to a maximum of 10 seconds. Treatment is continued for one month, or until repigmentation occurs, which is a much shorter time than PUVA therapy, which typically takes 6 months before any result is seen. Repigmentation is the appearance of brown pigment in the treated area, and is documented by standardized photography. In preliminary trials, four out of five patients receiving treatment for a minimum of nine sessions showed some response. This is a significant and substantial improvement in success rate over PUVA, glucocortoids, or any other current therapy for vitiligo. The repigmented skin is also relatively more permanent than other treatments such as sunscreens and cosmetic cover-ups, and will not rub-off.

When compared to standard phototheraphy, the 308 nm excimer laser has the advantage of having increased precision and the ability to deliver higher energy fluences thereby decreasing treatment time.

EXAMPLES

The following are intended as non-limiting examples of the invention.

Six men and twelve women with multiple discreet chronic stable patches of vitiligo enrolled in the study. Most patients had received and failed a variety of prior therapies for vitiligo (Table 1). No patient received any additional vitiligo therapy for at least one month prior to and during the study.

Eighteen patients started the study with a total of twenty-nine treated vitiligo patches. All patients had untreated vitiligo patches that were used as controls. Test areas of vitiligo were treated using a 308-nm xenon chloride excimer laser. A 120-ns, 20-hz, pulse was used with a 10-mm by 10-mm spot size and a power output of 60 mw of laser light. Lesions were treated three times a week for a maximum of 12 treatments. Exposure time was started at 2 seconds and increased by 2 seconds at every other visit until complete repigmentation occurred or until the protocol (12 treatments) was completed. Treatment was withheld if sunburn was observed and held until resolution.

Treated areas were evaluated for repigmentation and erythema on separate four point scales. Repigmentation was graded on the percentage of treated area of repigmentation as follows: 0:0%, 1:1–25%, 2:26–75% and 3:76–100%. Sunburn (erythema) was similarly graded as follows: 0—None, 1—Mild, 2—Moderate, 3—Severe. Patients with no repigmentation were defined as non-responders.

Results

Twelve patients with 23 patches completed at least six treatments. Six patients with 11 patches of vitiligo completed all twelve treatments that required an average of four weeks to complete. Six patients dropped out of the study before completion of six treatments and resulted in one slight repigmentation and five non-responders. Two of the non-responders developed mild erythema. Twelve patients with six or more total treatments of 23 vitiligo patches resulted in partial repigmentation in 57% of twenty-three patches. Six patients who completed twelve treatments of 11 vitiligo patches resulted in partial repigmentation in 87% of eleven patches (FIG. **4**). There were no serious adverse events. Mild sunburn with persistent erythema lasting up to three weeks was observed in some patients. Patients with the most repigmentation were skin-types III–VI. Table 1 sets forth the results.

TABLE 1

Demographics and Study Results of Patients Involved In the Protocol

Patient	Sex	Skin Phototype	Prior Treatment	Treatment Locations	Treatments Received	% Repig-mentation*	Erythema**
1	M	V	TS	Periocular	5	3	0
				Forearm	12	3	0
2	F	III	PUVA	Periocular	12	1	0
				Back	12	1	0
				Hand	12	0	0
				Thigh	12	1	0
3	F	I	None	L. Forearm	12	1	1
4	F	III–IV	None	L. Preauricular	9		
5	M	II	None	L. Neck	3	0	1
6	F	II	TS. Folate	L. Hand	5	1	0
7	F	IV	PUVA	Finger	12	0	0
8	M	II	TS	Abdomen	3	0	1
9	F	VI	TS	R. Temple	2	0	0
10	F	II	None	R. Wrist	6		
11	F	III–IV	None	R. Axilla	8	1	1
				Sternum	8	1	1
12	F		None	R. Axilla	1	0	0
13	M	III–IV	None	Chin	10	0	1
				L. Elbow	10	0	1
				L. Arm	10	0	1
14	M	II	PUVA	L. periocular	10	0	1
				R. Elbow	10	1	0
				Chin	10	0	1
15	F	II	PUVA	L. Shin	9	1	0
				L. Elbow	9	0	1
16	F	II	TS	Forearm	5	0	0
17	M	IV	PUVA	Forehead	12	1	0
				Chin	12	1	0
18	F	V	None	Elbow	12	2	0

*Repigmentation: 0 = 0; 1 = 1–25%; 2 = 26–75%; 3 = 76–100%
**Erythema: 0 = none; 1 = mild; 2 = moderate; 3 = severe

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention. All patent applications, patents, patent publications and literature references cited in this specification are hereby incorporated by reference in their entirety.

What is claimed is:

1. A method of treating vitiligo comprising the steps of:

(A) identifying an area of skin with an absence of melanin,

(B) exposing said area of skin to laser light in the UVB range for 10 seconds or less, and

(C) repeating said exposure until said skin is repigmented.

2. The method of claim **1** wherein the wavelength of said laser light is 308 nm, and the intensity of said laser light is 60 mwatts.

3. The method of claim **2** wherein said area of skin is exposed at least 3 times a week.

4. The method of claim **1** wherein the wavelength of said laser light is 290 to 320 nm.

5. The method of claim **4** wherein the intensity of said laser light is not more than 120 mwatts.

6. The method of claim **2** or **5** wherein said area of skin is exposed 1–5 times a week.

7. The method of claim **1** wherein each exposure of said area of skin to laser light occurs for an incrementally increased time period.

8. The method of claim **1** which comprises stimulating melanin production in said area of skin with said repeated exposures.

9. A method of treating vitiligo comprising the steps of;

(A) identifying an area of skin with an absence of melanin,

(B) first exposing said area of skin to UVB laser light for 1–5 seconds,

(C) increasing the length of exposure of said area of skin by 1–3 seconds after every two exposures until said area of skin is repigmented.

10. The method of claim **9** wherein the UVB laser light is generated by an excimer laser.

11. The method of claim **10** wherein the wavelength of said laser light is 308 nm, and the intensity of said laser light is 60 mwats.

12. The method of claim **11** wherein said area of skin is exposed at least 3 times a week.

13. The method of claim **9** wherein the wavelength of said laser light is 290–320 nm.

14. The method of claim **13** wherein the intensity of said laser light is no more than 120 mwatts.

15. The method of claim **14** wherein said area of skin is exposed 1–5 times a week.

16. A method of treating vitiligo comprising the steps of:

(A) identifying an area of skin with an absence of melanin,

(B) repeatedly exposing said area of skin to excimer laser light having a wavelength of 308 nm and an intensity of 60 mwatts,

(C) exposing said area of skin to said laser light 1–5 times a week for not more than 5 seconds during the first exposure; and

(D)) gradually increasing the exposure time to a maximum of 10 seconds per exposure.

17. A method of treating vitiligo comprising the steps of;

(A) identifying an area of skin with an absence of melanin,

(B) repeatedly exposing said area of skin to laser light having a wavelength of 290 to 320 nm and an intensity not more than 120 mwatts,

(C) exposing said area of skin to said laser light 1–5 times a week for not more than 5 seconds during the first exposure; and

(D) gradually increasing the exposure time to a maximum of 10 seconds per exposure.

18. A method of treating vitiligo comprising the steps of;

(A) identifying an area of skin with an absence of melanin,

(B) repeatedly exposing said area of skin to excimer laser light having a wavelength of 308 nm and an intensity of 60 mwatts,

(C) exposing said area of skin at least 3 times a week for 2 seconds during the first exposure; and

(D) increasing the exposure time by 2 seconds after every two exposures.

19. A method of treating vitiligo comprising the steps of:

(A) identifying an area of skin with an absence of melanin,

(B) exposing said area of skin to laser light in the UVB range for between 1 and 5 seconds, and

(C) repeating said exposure until said skin is repigmented.

* * * * *

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Vitiligo
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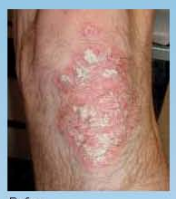
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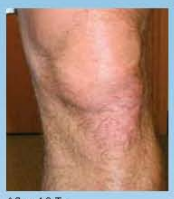
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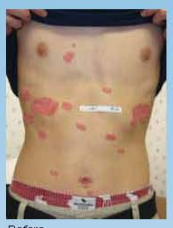
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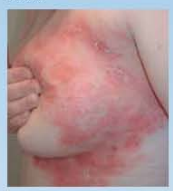
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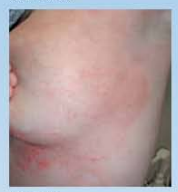
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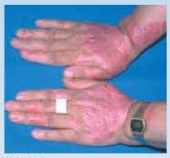
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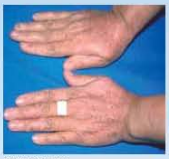
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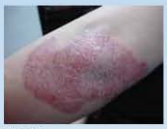
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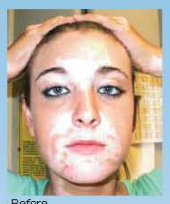
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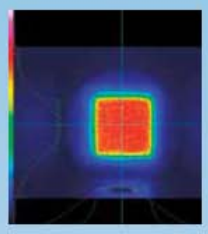
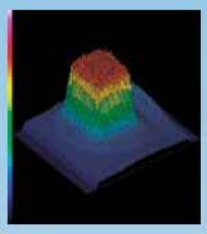
The unique integrated adjustable spot size and aiming beam accurately targets only the diseased tissue while sparing the healthy skin from exposure.

By gently sliding the finger-switch, the laser beam is easily contoured to match the size and shape of the plaque for fast and precisely targeted treatments with constant fluence. No templates or attachments required.





Beam Profile

PHAROS' proprietary optical lens design collimates the laser beam and reduces scatter for maximum clinical efficacy. The flat-top beam profile with no "hot-spots" delivers uniform doses for optimal patient comfort and results.

The PHAROS is small enough for any treatment room:
14" Wide x 27" Long x 32" Tall
It weighs 106 lbs and uses a standard 110-wall outlet.

PHAROS treatments are highly reimbursed and create a new profit center from your existing patient base

Almost all insurers including Medicare, Blue Cross/Blue Shield, United Healthcare, Cigna, and Aetna pay about $150 to $250 per treatment under laser CPT codes 96920, 96921, and 96922.

Each patient can generate about $2250 to $7500 each year for the practice.
Treating just a few patients each month can generate more than $150,000 annually.

Ra Medical Systems, Inc.
Tel: (760) 804-1648
www.ramed.com
info@ramed.com

Ra™ medical systems

P/N 10-100-84-10110002 R1

specialist, to address these needs. Each program includes custom trainings, policies and procedures.

compr
repair sc
workflo
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Ra Medical™ SYSTEMS

BRONZE SPONSOR
EXHIBITOR & CORPORATE MEMBER

EXHIBIT

Jim Greer

Ra Medical Systems, Inc., markets the PHAROS EX-308, an advanced 308-nm super narrowband UVB excimer laser for psoriasis, vitiligo, atopic dermatitis, and leukoderma. It is ideal for localized, recalcitrant, and difficult-to-treat psoriasis including scalp, palms and soles, and intertriginous lesions and for localized vitiligo, including facial and peri-orbital areas.

Revision
quality
purpose
problem
cosmec
targete
designe
conditi
They u
quality


Pharos™
Excimer Laser
Psoriasis • Vitiligo • Atopic Dermatitis
by Ra Medical SYSTEMS
Pharos™
Excimer Laser
Psoriasis
Vitiligo
Atopic Dermatitis
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EXHIBIT B

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As filed with the Securities and Exchange Commission on July 16, 2018

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT

Under

The Securities Act of 1933

Ra Medical Systems, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	3841	38-3661826
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2070 Las Palmas Drive
Carlsbad, California 92011
(760) 804-1648

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Dean Irwin
Chief Executive Officer, Chairman of the Board, Co-President, and Chief Technology Officer
Ra Medical Systems, Inc.
2070 Las Palmas Drive
Carlsbad, California 92011
(760) 804-1648

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Martin J. Waters	Joshua A. Kaufman
Wilson Sonsini Goodrich & Rosati, P.C.	Divakar Gupta
12235 El Camino Real,	Charles Bair
San Diego, California 92130	Cooley LLP
(858) 350-2300	1114 Avenue of the Americas
	New York, New York 10036
	(212) 479-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[(1)(2)]	Amount of Registration Fee
Common Stock $0.0001 par value per share	$86,250,000	$10,738.13

(1) Includes offering price of any additional shares that the underwriters have the option to purchase.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **(Subject to Completion, Dated July 16, 2018)**

Shares

Common Stock

This is the initial public offering of shares of common stock by Ra Medical Systems, Inc. No public market for our common stock currently exists. We are offering all of the shares of common stock offered by this prospectus. We expect the initial public offering price to be between $ and $ per share.

We have applied to list our common stock on the New York Stock Exchange under the symbol "RMED."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common shares in "Risk factors" beginning on page 13 of this prospectus.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts[1]	$	$
Proceeds, before expenses, to us	$	$

[1] We refer you to "Underwriting" beginning on page 154 for additional information regarding total underwriting compensation.

The underwriters may also purchase up to an additional shares of common stock from us at the public offering price, less the underwriting discounts payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus.

The underwriters expect to deliver the shares of common stock to investors on or about , 2018.

Piper Jaffray **Cantor**

SunTrust Robinson Humphrey

Nomura

, 2018

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Through and including (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

For investors outside the U.S.: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the U.S. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary may not contain all the information you should consider before investing in our common stock. You should carefully read this prospectus in its entirety before investing in our common stock, including the sections titled "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" and our financial statements and related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms "Ra Medical," "Ra Medical Systems," "the Company," "our company," "we," "us," and "our," refer to Ra Medical Systems, Inc.

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of the DABRA laser system and disposable catheter, together referred to as DABRA, in the United States. Following the temporary placement period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements, or Usage Agreements, with each customer. As of June 30, 2018, we had a U.S. installed base of 31 DABRA laser systems, eight of which have signed Usage Agreements with us, and the remainder of which are temporarily placed for use in demonstrations, trials, or training. DABRA is cleared by the U.S. Food and Drug Administration, or FDA, as a tool for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease, which includes peripheral artery disease, or PAD, which commonly occurs in the legs. We intend to pursue additional uses for DABRA, including seeking regulatory clearance for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other venous and arterial occlusions, or blockages in the veins or arteries. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA. DABRA is our minimally-invasive excimer laser and disposable catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and

obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging.

DABRA is a novel technology for use in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease. We believe that our liquid-filled, full aperture ratio catheter allows for a less traumatic endovascular treatment for the removal of vascular blockages and offers significant benefits over competing treatments and therapies. DABRA is easy to use and can cross and debulk, or reduce or remove, a broad range of blockage types without the use of a guidewire. Although DABRA is suitable for use as a monotherapy, or a therapy that uses one type of treatment, it is predominantly used with angioplasty balloons and also can be used adjunct to drug-eluting balloons, stents, and other endovascular treatments.

In May 2017, we received FDA 510(k) clearance to market the DABRA laser system and disposable DABRA catheter in the U.S. for intended use in ablating a channel in occlusive peripheral vascular disease. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of DABRA in the United States. We market DABRA in the U.S. through our direct sales force comprised of 15 sales representatives as of June 30, 2018, which places lasers in catheterization laboratories that perform high volumes of endovascular procedures, including atherectomy on peripheral arteries. We have plans to increase sales by further expanding this organization. DABRA was granted CE mark clearance in September 2016, and we sell systems through distributors in select non-U.S. countries.

Pharos. Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. We have also received clearance to market Pharos from the European Medicines Agency, or EMA, China Food and Drug Administration, or CFDA, and South Korea Ministry of Drug Safety, or KFDA in the applicable jurisdictions. Pharos offers significant benefits to patients. The targeted nature of our treatment allows the operator to spare healthy tissue from exposure to the ultraviolet light making the treatment faster and safer than some other forms of phototherapy, or light therapy. The light induces T-cell apoptosis, or cell death, which we believe may produce an immunosuppressant effect.

Our Strategy

Our goal is to become the leading medical device company marketing excimer lasers as tools for the treatment of endovascular diseases. Key elements of our strategy to achieve this goal are:

- ***Driving physician awareness of DABRA.*** Our program to educate physicians regarding DABRA's value proposition consists of presentations and exhibits at industry conferences, advertising in medical journals, direct visits, webinars, and calls.
- ***Creating patient awareness of DABRA.*** We are establishing marketing and support programs with physicians and patient advocacy organizations to create patient awareness of PAD treatment options in order to generate demand for our products.
- ***Expanding DABRA sales.*** We provide physicians with clinical training to drive adoption and utilization of DABRA. We believe that a strong sales team to train physicians on the use and the benefits of DABRA will increase sales. We expect to continue to expand the clinical sales team through 2018 and beyond.

- ***Extending DABRA to additional indications.*** We plan to leverage our product technology and research and development expertise to develop DABRA for additional vascular indications, such as CAD and in-stent restenosis.
- ***Expanding commercial opportunities for DABRA internationally***. We received the right to affix the CE mark to DABRA in the third quarter of 2016, permitting DABRA to be marketed and sold in Europe and other CE mark markets. We plan to expand commercial opportunities for DABRA internationally through obtaining additional regulatory approvals and expanding our relationships with international distributors.
- ***Optimizing existing manufacturing capabilities to generate operating leverage***. We design, develop and manufacture DABRA in-house using components and sub-assemblies provided by third-party suppliers. We believe that by controlling the manufacturing and assembly of our products we are able to innovate more quickly, produce higher quality products, and increase our manufacturing scale in a cost-effective manner. We intend to use our design, engineering, and manufacturing capabilities to further improve the efficiency of our manufacturing process and expand our margins.
- ***Expanding our product offerings.*** We believe that we will be able to leverage our technology and sales platform to expand our endovascular offerings with ancillary endovascular devices such as angioplasty balloons, guide catheters, and introducers. We intend to achieve this through our internal development efforts and with selective licenses, alliances or acquisitions of complementary products, technologies or businesses.

Strengths of our Approach—DABRA

DABRA includes a portable excimer laser system combined with proprietary, single-use catheters that, together, represent a competitive atherectomy solution for the minimally invasive endovascular treatment of blockages in the vasculature, or blood vessels such as arteries or veins. DABRA represents a novel approach to the treatment of a broad range of vascular blockages that is safe and effective, easy to use, and competitively priced. We believe that the principal benefits of DABRA are:

- ***Safety.*** DABRA is designed to track the patient's true lumen, or the center of the artery, and not to penetrate between the layers of arterial structure known as the subintimal space. Damage or stretching of the arterial walls, which can lead to dissection, or a tear in the inner lining of the vessel wall, or perforation, or a hole or a break in the vessel wall, may be reduced. No serious adverse events were reported in our 2017 pivotal study, which followed 38 subjects for 180 days, or reported in our post-market surveillance for DABRA. In our post-market surveillance, the most frequent complication reported to us has been clinically non-significant vessel perforation.
- ***Efficacy.*** Unlike many treatments for PAD that do not remove plaque, DABRA employs photochemical ablation, or the removal of body tissue by using photons, to disintegrate plaque by breaking its chemical bonds, thereby reducing the plaque to the components of its fundamental chemistry without generating potentially harmful particulates. We believe that eliminating plaque while minimizing injury to the arterial wall may minimize the rate of restenosis, or the re-accumulation of blockages. We followed 38 subjects from our pivotal study to 180 days thereafter and all of the

subjects were determined to be completely free of target lesion revascularization, or the need to retreat the lesion.

- ***Utility.*** DABRA enables physicians to remove plaque from long and calcified lesions in arteries located in the lower extremities both above- and below-the-knee. DABRA is able to cross and debulk a wide variety of plaque, removing vascular blockages that other products are unable to cross without the use of a guidewire. For example, in patients with a chronic total occlusion, or CTO, the physician may use DABRA to cross the CTO prior to alternative treatments consisting of balloon angioplasty and possibly stenting.
- ***Ease of Use.*** DABRA employs techniques similar to those used in angioplasty, which are familiar to the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the U.S. who are generally trained in endovascular techniques. This significantly increases the number of physicians who are able to perform the procedure compared to surgical alternatives that must be performed by highly-trained vascular surgeons.
- ***Cost and Time Efficient.*** We believe that because our single-use DABRA catheters are priced competitively and because we provide the DABRA laser system for a nominal monthly fee, without requiring the purchase of capital equipment, DABRA is a cost-effective solution for providers. Providers are also eligible for reimbursement for procedures performed using DABRA using existing Current Procedural Terminology, or CPT, codes. In addition, DABRA's easy setup and fast ablation speed reduce both treatment and fluoroscopy time, or x-ray exposure time, for the patient, physician, and staff, improving the providers' patient throughput. The average lasing time in our pivotal study was approximately two and a half minutes per procedure.
- ***Immunotherapeutic Benefits.*** Research performed using 308 nanometer laser energy, the wavelength of Pharos, demonstrated increased T-cell apoptosis, which may produce an immunosuppressant effect. Unlike with Pharos, where we can measure the degree and speed of clearance of disease and quantify the remission time, with DABRA we have not established the benefits of this immunosuppressant effect in the vasculature. We intend to conduct a registry or study to identify any immunotherapeutic benefits.

Strengths of our Approach—Pharos

Pharos is an excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders, such as psoriasis, vitiligo, atopic dermatitis, and leukoderma. We believe that the principal benefits of Pharos are:

- ***Wavelength.*** Studies have shown that the action spectrum, or the rate of a physiological activity plotted against wavelength of light, for immunologically modulated skin disorders is centered at about 308 nanometers. Pharos is a 308 nanometer laser, making it ideally suited for use as a tool in the treatment of these disorders.
- ***Energy.*** The energy from excimer lasers has been shown, in both in vivo and in vitro studies, to have almost four times the T-cell apoptosis generation than non-laser sources. Pharos is a pulsed laser capable of producing very high peak powers and we believe that this may produce an immunosuppressive effect.

- ***Collimation.*** Ultraviolet-B light has a very shallow penetration into the skin, typically less than 100 microns. Although the skin tends to scatter the light, collimation, or keeping the light rays parallel, helps prevent reflection and improves the dose delivery. Pharos has a moderately collimated beam and this collimation allows for treatment in intertriginous areas, such as the groin and armpits, and mucosal areas, such as the mouth and ears, without compromising dose.
- ***Targeting.*** Applying the laser energy only to the diseased tissue not only spares the healthy tissue from exposure, but also allows the operator to increase the dose to the affected areas. We believe that Pharos is the only system that has an integrated adjustable spot size offering continuous beam adjustment from a large square to a small circle.
- ***Footprint.*** Dermatological treatment rooms are small and often crowded with other equipment. Pharos has a small footprint and is among the lightest excimer lasers currently marketed, allowing physicians to conserve space and easily move the system.

Risks Associated with our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section captioned “Risk factors” immediately following this prospectus summary. You should read these risks before you invest in our common stock. In particular, risks associated with our business include, but are not limited to, the following:

- We have incurred losses in each of the last two years and may be unable to return to profitability in the future.
- We may be unable to achieve revenue growth.
- Our success depends in large part on DABRA. If we are unable to successfully market and sell DABRA, our business prospects will be significantly harmed.
- We will require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms, or at all. As a result, we may not be able to continue our marketing efforts to increase the adoption of our products.
- Our products may not gain or maintain market acceptance among physicians and patients and others in the medical community.
- The continuing development of our products depends upon our maintaining strong working relationships with physicians.
- If our manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to manufacture and sell our products and to pursue our research and development efforts may be jeopardized.
- We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us.
- If DABRA and Pharos are not approved for new indications, our commercial opportunity will be limited.
- If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology may be adversely affected.

- Third parties may claim that the manufacture, use or sale of our products infringe their intellectual property rights.
- Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business.
- Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.
- We may not be able to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and acceptable market share for DABRA and Pharos.
- If critical components used in manufacturing our products become scarce or unavailable, we may incur increased costs and delays in the manufacturing and delivery of our products, which could damage our business.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.
- We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Corporate and other Information

We were incorporated in California on September 4, 2002, and reincorporated in Delaware in July 2018. Our principal executive offices are located at 2070 Las Palmas Drive, Carlsbad, California 92011 and our telephone number is (760) 804-1648 or (877) 635-1800 toll-free. Our corporate website address is www.ramed.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

We own or have rights to trademarks that we use in connection with the operation of our business. Ra Medical Systems, Inc. and our logo as well as other trademarks such as DABRA and Pharos, are used in this prospectus. Solely for convenience, the trademarks referred to in this prospectus are listed without trademark symbols, but we will assert, to the fullest extent under applicable law, our rights to these trademarks. Additionally, we do not intend for our use or display of other companies' trademarks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

Implications of being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, enacted in April 2012. An "emerging growth company" may take

advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of "Selected financial data" and related "Management's discussion and analysis of financial condition and results of operations" in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares
Underwriters' option to purchase additional shares	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to an additional shares of common stock from us.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately $ million based upon an assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering for the expansion of our direct sales force and marketing of our products, to support clinical studies for new products and product enhancements including for expanded indications, and to support other research and development activities, working capital, and general corporate purposes. We may also use a portion of the net proceeds of this offering for acquisitions to bolster our product offerings. We have not entered into any agreements or commitments with respect to any specific acquisitions and have no understandings or agreements with respect to any such acquisition or investment at this time. See "Use of proceeds" for additional information.
Risk factors	You should carefully read the "Risk factors" section of this prospectus beginning on page 13 for a discussion of factors that you should consider before deciding to invest in our common stock.
Proposed New York Stock Exchange trading symbol	"RMED"

The number of shares of our common stock to be outstanding after this offering is based on 7,944,251 shares of our common stock outstanding as of March 31, 2018, and excludes:

- 1,892,000 shares of common stock issuable upon exercise of outstanding options that were issued following March 31, 2018 at an exercise price of $28.94 per share under our 2018 Stock Compensation Plan, or our Compensation Plan;

- 1,337,722 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units that were issued following March 31, 2018 under our Compensation Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of:
  - 70,278 shares of common stock reserved for future issuance under our Compensation Plan as of July 13, 2018, which shares will be added to the shares to be reserved under our 2018 Equity Incentive Plan, or our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for future issuance under our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for issuance under our 2018 Employee Stock Purchase Plan, or ESPP, which will become effective upon the completion of this offering; and
  - any shares that become available for future issuance under our 2018 Plan and ESPP, pursuant to provisions that automatically increase the reserves under such plans each year.

Unless otherwise noted, the information in this prospectus assumes:

- a -for-one split of our common stock, to be effected before the closing of this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws in connection with the completion of this offering;
- no exercise of outstanding options subsequent to March 31, 2018; and
- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock in this offering.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data for the periods and as of the dates indicated. We have derived the statements of operations data for the years ended December 31, 2016 and 2017 from our audited financial statements included elsewhere in this prospectus. We have derived the statements of operations data for the three months ended March 31, 2017 and 2018, and the balance sheet data as of March 31, 2018 from our unaudited interim financial statements included elsewhere in this prospectus. We have prepared the unaudited interim financial statements on the same basis as the audited financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future and the results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the full year or any other period. You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the sections titled "Selected financial data" and "Management's discussion and analysis of financial condition and results of operations."

	Year Ended December 31,		Three Months Ended March 31,	
	2016	2017	2017	2018
	(in thousands, except per share data)			
Statement of Operations Data:				
Net revenue	$ 5,976	$ 5,870	$ 1,065	$ 969
Cost of revenue	3,138	4,165	602	736
Gross profit	2,838	1,705	463	233
Operating expenses:				
Selling, general and administrative	5,321	14,947	1,745	2,639
Research and development	1,715	4,518	379	286
Total operating expenses	7,036	19,465	2,124	2,925
Operating loss	(4,198)	(17,760)	(1,661)	(2,692)
Interest expense	3	4	1	1
Income tax expense	1	1	—	—
Net loss	(4,202)	(17,765)	(1,662)	(2,693)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.60)	$ (2.35)	$ (0.22)	$ (0.34)
Weighted-average shares outstanding, basic and diluted	6,951	7,545	7,463	7,938

	As of March 31, 2018		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 7,083	$ 13,583	$
Working capital[4]	5,925	12,425	
Total assets	10,606	17,106	
Accumulated deficit	(32,082)	(32,082)	
Total stockholders' deficit	(8,907)	(2,407)	

footnotes on following page

(1) Pro forma amounts reflect the issuance of 260,000 shares of common stock in exchange for $6.5 million of proceeds received in our private placement of common stock subsequent to the historical periods presented.
(2) Pro forma as adjusted amounts reflect the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
(3) A $1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming the number of shares offered by us as stated on the cover of this prospectus remain unchanged and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
(4) We defined working capital as current assets less current liabilities.

Non-GAAP Measures

EBITDA and Adjusted EBITDA are performance measures that provide supplemental information we believe is useful to analysts and investors to evaluate our ongoing results of operations, when considered alongside other GAAP measures. These non-GAAP Measures exclude the financial impact of items management does not consider relevant in assessing our ongoing operating performance, and thereby facilitate review of our operating performance on a period-to-period basis. Comparability to our results of operations to other companies may be impacted by our stock-based compensation which was classified as a liability and revalued at each reporting period with the change in fair value recorded to compensation expense in the statement of operations.

We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. Some of these limitations are that:

- EBITDA excludes certain recurring, non-cash charges such as deprecation of fixed assets and amortization of acquired intangible assets and, although these are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future; and
- Adjusted EBITDA further excludes stock-based compensation expense, which has been, and will continue to be for the foreseeable future, a significant recurring expense in our business and an important part of our compensation strategy, as well as certain non-recurring items which may affect comparability of our core operations such as the loss on abandonment of facility.

In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison.

A reconciliation for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with U.S. GAAP is included below. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business. We define Adjusted EBITDA as our GAAP net loss as adjusted to exclude depreciation, amortization, interest expense, income tax expense, stock-based compensation and loss on abandonment of facility.

The following table presents a reconciliation of Adjusted EBITDA to net loss, the most comparable GAAP financial measure, for each of the periods presented:

	Year Ended December 31,		Three Months Ended March 31,	
	2016	2017	2017	2018
	(in thousands)			
Statement of Operations Data:				
Net loss	$(4,202)	$(17,765)	$(1,662)	$(2,693)
Depreciation and amortization	95	218	32	96
Interest expense	3	4	1	1
Income tax expense	1	1	—	—
EBITDA	(4,103)	(17,542)	(1,629)	(2,596)
Stock-based compensation	2,300	12,706	426	524
Loss on abandonment of facility	—	212	—	—
Adjusted EBITDA	$(1,803)	$ (4,624)	$(1,203)	$(2,072)

The pro forma as adjusted information discussed above is illustrative only and will be revised based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all of the other information contained in this prospectus, including our financial statements and related notes, before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to our Business and Products

We have incurred losses in each of the last two years and may be unable to return to profitability in the future.

We incurred net losses of $4.2 million and $17.8 million for the years ended December 31, 2016 and 2017, respectively, and $1.7 million and $2.7 million for the three months ended March 31, 2017 and 2018, respectively. As a result of these losses, as of March 31, 2018, we had an accumulated deficit of $32.1 million. We expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand our marketing efforts to increase adoption of our products and expand existing relationships with our customers, to obtain regulatory clearances or approvals for our products in additional jurisdictions and for additional indications, and to develop new products or add new features to our existing products. In addition, we expect our general and administrative expenses to increase following this offering due to the additional costs associated with being a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenues in order to achieve and sustain profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or return to profitability would have a material adverse effect on our business, financial condition, and results of operations and could negatively impact the value of our common stock.

We may be unable to achieve revenue growth.

Our ability to grow our revenue in future periods will depend on our ability to successfully penetrate our target markets and increase sales of our products and any new product indications that we introduce, which will, in turn, depend in part on our success in growing our installed unit base and driving continued use of our systems. New product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies to drive revenue growth. If we cannot achieve revenue growth, it could have a material adverse effect on our business, financial condition, and results of operations.

Our success depends in large part on DABRA. If we are unable to successfully market and sell DABRA, our business prospects will be significantly harmed.

Our future financial success will depend substantially on our ability to effectively and profitably market and sell DABRA. The commercial success of DABRA will depend on a number of factors, including the following:

- the effectiveness of our and our distributors' marketing and sales efforts in the U.S. and abroad, including our efforts to build out our sales team;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing treatments;

- the availability of coverage and adequate levels of reimbursement under private and governmental health insurance plans for DABRA-based procedures;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to DABRA;
- achieving and maintaining compliance with all regulatory requirements applicable to DABRA;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices, or cGMP; and
- whether we are required by the FDA, EMA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

If we fail to successfully market and sell DABRA, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition, and results of operations.

We will require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. As a result, we may not be able to continue our marketing efforts to increase the adoption of our products.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and marketing efforts. We expect our sales and marketing expenses to increase substantially in connection with our plan to commercialize DABRA in the U.S. and internationally. These expenditures will also include costs associated with manufacturing and supply, sales and marketing costs, and general operations. In addition, other unanticipated costs may arise.

As of March 31, 2018, we had cash and cash equivalents of $7.1 million. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months.

The amount and timing of any expenditures needed to implement our sales and marketing programs will depend on numerous factors, including, but not limited to:

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and acceptable market share for DABRA and Pharos;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights; the emergence of competing technologies and other adverse market developments;
- the costs associated with manufacturing, selling, and marketing DABRA and Pharos for their cleared or approved indications or any other indications for which we receive regulatory clearance or approval, including the cost and timing of expanding our manufacturing capabilities, as well as establishing our sales and marketing capabilities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, our future products or future improvements on our existing products, if any;

- the time and cost necessary to complete post-marketing studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, as we become a public company.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our products, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend our sales and marketing efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

Our products may not gain or maintain market acceptance among physicians and patients and others in the medical community.

Our success will depend, in part, on the acceptance of our products as safe, useful and, with respect to physicians, cost effective. We cannot predict how quickly, if at all, catheterization laboratories and physicians will accept our products or, if accepted, how frequently they will be used. Patients and their care providers must believe our products offer benefits over alternative treatment methods. Additional factors that will influence whether our products gain and maintain market acceptance, include:

- whether physicians, catheterization laboratory owners and operators, patients, and others in the medical community consider our products safe, effective, and cost effective treatment methods;
- the potential and perceived advantages of our products over alternative treatment methods;
- the prevalence and severity of any side effects associated with using our products;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities;
- limitations or warnings contained in the labeling cleared or approved by the FDA, EMA or other authorities;
- the cost of treatment in relation to alternative treatments methods;
- the convenience and ease of use of DABRA and Pharos relative to alternative treatment methods;
- pricing pressure, including from group purchasing organizations, or GPOs, seeking to obtain discounts on DABRA and Pharos based on the collective buying power of the GPO members;
- the availability of adequate coverage, reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;

- our ability to provide incremental clinical and economic data that shows the safety and clinical efficacy and cost effectiveness of, and patient benefits from, our products; and
- the effectiveness of our sales and marketing efforts for DABRA and Pharos.

If we do not educate physicians about PAD and the existence of our products, DABRA may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for CAD. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost effective. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition, and results of operations.

The continuing development of our products depends upon our maintaining strong working relationships with physicians.

The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the U.S. Department of Justice, or DOJ. Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations. Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below in the Risk Factor captioned *"Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings."*

Physicians and staff may not commit enough time to sufficiently learn how to use our products.

In order for physicians and staff to learn to use our products, we encourage physicians to attend structured training sessions in order to familiarize themselves with our technology. There are many nuances to using our products as intended. For example, the DABRA catheter is fragile and may be prone to bending at the entry of the artery, a problem known as kinking. Further, physicians and their staff must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use our products. Market acceptance of DABRA could be delayed by lack of physician or staff willingness to attend training sessions or familiarize themselves with DABRA. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse effect on our business, financial condition, and results of operations.

If our sole manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to manufacture and sell our products and to pursue our research and development efforts may be jeopardized.

We currently manufacture and assemble our products in our sole manufacturing facility in Carlsbad, California. Our products consist of components sourced from a variety of suppliers, with final assembly completed at our facility. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, fires, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, extreme weather conditions, medical epidemics, and other natural or man-made disasters or other business interruptions, for which we are predominantly self-insured. Any of these may render it difficult or impossible for us to manufacture products for an extended period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products. We also rely on third-party component suppliers, and our ability to obtain commercial supplies of our products could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, which would have a material adverse effect on our business, financial condition, and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products.

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians in connection with the use of our products on patients. If these physicians are not properly trained or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;

- exhaustion of any available insurance and our capital resources;
- the inability to market and sell our products; and
- a decline in the price of our common stock.

We believe our product liability insurance is customary for similarly situated companies, but it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us.

The medical device industry is intensely competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may also develop products that are more effective, more convenient, more widely used, less costly, or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology, which would have a material adverse effect on our business, financial condition, and results of operations.

We may be unable to compete successfully with larger companies in our highly competitive industry.

The healthcare industry is highly competitive. There are numerous approved products for treating vascular and dermatological diseases in the indications in which we have received clearance or approval and those that we may pursue in the future. Many of these cleared or approved products are well-established and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future.

Our primary competitors for DABRA include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., or Philips, including Volcano Corporation and Spectranetics Corporation, including products from the C.R. Bard acquisition, and Abbott Laboratories. These companies are manufacturers of products used in competing therapies within the peripheral and coronary atherectomy markets such as:

- atherectomy, using mechanical methods to remove vascular blockages;

- balloon angioplasty and stents;
- specialty balloon angioplasty, such as scoring balloons, pillowing balloons, cutting balloons and drug-coated balloons;
- bypass surgery; and
- amputation.

We are also subject to competition from pharmaceutical companies that produce drugs which aim to destroy plaque or remove blockages in the bloodstream.

Our primary competitors for Pharos are Daavlin, National Biological, STRATA Skin Sciences and large pharmaceutical companies producing biologicals used in the treatment of chronic skin conditions.

Many of our competitors have substantially greater financial, manufacturing, commercial, and technical resources than we do. There has been consolidation in the industry, and we expect that to continue. Larger competitors may have substantially larger sales and marketing operations than we do. This may allow those competitors to spend more time with current and potential customers and to focus on a larger number of current and potential customers, which gives them a significant advantage over our sales and marketing team and our international distributors in making sales. In addition, we are often selling to customers who already utilize our competitors' products and who have established relationships with our competitors' sales representatives and familiarity with our competitors' products.

Larger competitors may also have broader product lines, which enables them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical trials, obtaining FDA and non-U.S. regulatory clearances or approvals and marketing cleared or approved products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. This may render our technology or products obsolete or noncompetitive. Our competitors may also be better equipped than we are to respond to competitive pressures. If we are unable to compete successfully in our industry, it would have a material adverse effect on our business, financial condition, and results of operations.

If DABRA and Pharos are not approved for new indications, our commercial opportunity will be limited.

We market and sell DABRA for use in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label. However, one of our strategies in the future is to pursue additional vascular indications for DABRA and additional dermatological indications for Pharos. Submitting the required applications for additional indications may require substantial additional funding beyond the net proceeds of this offering. We cannot assure you that we will be able to successfully obtain approval for any of these additional product indications through the application process.

Even if we obtain FDA clearance or approval to market our products for additional indications in the U.S., we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop our products for additional indications, our commercial opportunity will be limited, which would have a material adverse effect on our business, financial condition, and results of operations.

We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

Additionally, since all of our products are manufactured at our facility in Carlsbad, any contamination of the controlled environment, equipment malfunction, or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources.

If our manufacturing activities are adversely impacted, or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition, and results of operations.

If we make acquisitions or divestitures, we could encounter difficulties that harm our business.

To date, the growth of our business has been organic, and we have no experience in acquiring other businesses, products or technologies. We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes. If we use our common stock to acquire companies, products or technologies, our stockholders may experience substantial dilution.

Technological change may adversely affect sales of our products and may cause our products to become obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could adversely affect sales of our products. Our products could be rendered obsolete because of future innovations by our competitors or others in the treatment of vascular diseases and dermatological diseases, which would have a material adverse effect on our business, financial condition, and results of operations.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

Many medical device industry companies are consolidating to create new companies with greater market power. For example, Spectranetics was acquired by Philips in August 2017. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices that incorporate components produced by us. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease and our

earnings, financial condition, or cash flows would suffer, which would have a material adverse effect on our business, financial condition, and results of operations.

Litigation and other legal proceedings may adversely affect our business.

From time to time we are involved in and may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action, and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

We must indemnify officers and directors, including, in certain circumstances, former employees and directors, against all losses, including expenses, incurred by them in legal proceedings and advance their reasonable legal defense expenses, unless certain conditions apply. A prolonged uninsured expense and indemnification obligation could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.

In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations.

For our sales and operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, U.K. Bribery Act, and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third parties, fail to comply with the FCPA and other anti-corruption and anti-bribery laws.

We leverage various third parties to sell our products and conduct our business abroad, including to government owned universities and hospitals. We, our distributors and channel partners, and our other third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses or sales to government owned or controlled health care facilities, universities, institutes, clinics, etc.) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, contractors, third parties, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations.

A variety of risks associated with marketing our products internationally could materially adversely affect our business.

In addition to selling our products in the U.S., we sell Pharos and DABRA outside of the U.S. We are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing reimbursement regimes in foreign countries, including price controls;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition, and results of operations.

We face additional credit and compliance risks related to our international sales using foreign distributors.

We partner with distributors for DABRA and Pharos in select geographies outside of the U.S. Specifically, in 2017 we sold to distributors located in the Netherlands, China, Thailand, United Arab Emirates, and Italy. In 2017, approximately 10% of our sales were outside of the U.S. We may not be able to collect all of the funds owed to us by our foreign distributors. Some foreign distributors may experience financial difficulties, including bankruptcy, which may hinder our collection of accounts receivable. Where we extend credit terms to distributors, we periodically review the collectability and creditworthiness when determining the payment terms for such distributors. If our uncollectible accounts exceed our expectations, this could adversely impact our operating results. In addition, failure by our foreign distributors to comply with the Foreign Corrupt Practices Act or similar laws, insurance requirements, or other contract terms could have a negative impact on our business. Failure to manage the risks related to our foreign distributors would have a material adverse effect on our business, financial condition, and results of operations.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive medical devices industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our senior management team. The loss of the services of any of our executive officers and other key employees, and our inability to find suitable replacements could result in delays in product development and harm our business.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our

company, in addition to salary and cash incentives, we have issued stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees, with the exception of the "key man" insurance policy for our Chief Executive Officer, Dean Irwin. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of DABRA and Pharos, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures and user errors, among other malfunctions. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Technological interruptions would impact our business operations would disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition, and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations

We have identified a material weakness in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal

control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction and a decrease in our stock price.

Following our initial public offering, we will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Such report will not be required until our second annual report filed on Form 10-K. We will need to disclose any material weaknesses identified by our management in our internal control over financial reporting. As an "emerging growth company," we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission, or SEC, or other regulatory authorities, which would require additional financial and management resources.

In prior periods we identified certain material weaknesses in our internal controls related to revenue recognition and lack of staffing in the accounting and finance organization. In connection with these prior material weaknesses we implemented remediation measures including training of accounting personnel as well as hiring additional personnel with experience in the ongoing identification, design and implementation of internal control over financial reporting.

In connection with our 2017 audit, as part of the restatement to the 2016 financial statements described in Note 3 to the financial statements, we identified a material weakness in the design of our internal controls related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication of stock option awards which were not validly authorized. While we have designed and implemented, or expect to implement, measures that we believe address this material weakness, we continue to develop our internal controls, processes and reporting systems by, among other things, hiring qualified personnel with expertise to perform specific functions, including our Chief Financial Officer, the engagement of third party legal counsel to assist in the administration of capital stock transactions, and designing and implementing improved processes and internal controls, including ongoing senior management review and board of directors oversight. We expect to continue to build a more experienced administrative organization with expertise to perform specific functions and to design and implement improved processes and internal controls. We have incurred significant costs to remediate these weaknesses, primarily personnel costs, external consulting and legal fees, system implementation costs, and related indirect costs including the use of facilities and technology, and we expect to incur additional costs to remediate these weaknesses. We may not be successful in implementing these remediation efforts or in developing other internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Further, we will not be able to fully assess whether the steps we are taking will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional errors that result in material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in

business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations.

We could be subject to claims based on defects with respect to certain corporate transactions that were not authorized in accordance with applicable law.

We have determined that due to the material weakness in our internal controls related to the administration of capital stock transactions, there have been defects with respect to certain corporate transactions, including (i) stock issuances that were not or may not have been properly approved by our board of directors and/or adequately documented, (ii) a reverse stock split for which we failed to file the amendment to our articles of incorporation, and (iii) the communication of option awards that were not validly authorized by our board of directors as a result of non-existent or defective board approvals, in each case in accordance with applicable law.

To remediate these defects, we have taken a number of actions. We have ratified the defective stock issuances; are in the process of obtaining agreements from our stockholders which includes a confirmation of the securities each stockholder holds, a release of potential claims with respect to issuance of securities to such stockholders, and a surrender specifically of any claims to the equity of the Delaware corporation except for the shares of the Delaware corporation that such stockholder has received in the reincorporation merger pursuant to the merger agreement; are in the process of confirming that the appropriate number of shares of common stock outstanding immediately prior to the time of the intended reverse stock split were contributed to the capital of the Company effective as of the intended time of, and to give effect to, the intended reverse stock split; and have approved compensation to and obtained releases from our impacted employees and other service providers to resolve potential claims, if any, related to the communicated grants of option awards and to promote retention and align their interests with the long-term interests of our stockholders. While we have attempted to narrow potential future claims by taking certain remedial corporate actions, the scope of liability with respect to such defects is uncertain and we cannot assure that these actions will entirely remediate these defects or that we will not receive claims in the future from other persons asserting rights to shares of our capital stock or to stock options or other equity. To the extent any such claims are successful, they could have a material adverse effect on our business, financial condition and results of operations.

Under certain authority, common law ratification by our board of directors of prior stock issuances may have caused such issuances to be valid stock issuances by us at the time of the respective issuances. However, there is uncertainty under applicable law as to whether such common law ratification may be effective under all circumstances. There can be no assurance that stockholders will not assert claims that a defective corporate act or putative stock issuance ratified by us is void or voidable due to the identified failure of proper authorization by our board of directors, as well as other claims related thereto, and, if asserted, that any such claims will not be successful. If such ratification is deemed not to be effective,

then the issuances of certain shares of our stock and other attempted corporate actions would be invalid and we could have liability to grantees of our common stock, which may have a material adverse effect on our business and results of operations.

We are also confirming that certain stockholders as of the time of the intended reverse stock split contributed a number of shares of common stock sufficient to give effect to the recapitalization intended by the reverse stock split. However, a holder of our common stock could argue that this process does not represent an adequate remedy for a potential failure to properly implement the reverse stock split. If the contribution of shares to the capital of the Company was not effective, then we could have liability to certain holders of our common stock, which may have a material adverse effect on our business and results of operations.

Additionally, we may have potential liability to certain of our employees, directors, consultants, and other service providers for communicated grants of option awards that were not authorized in compliance with applicable law. With respect to the communicated grants of option awards that were not validly authorized, we approved compensation and obtained a release of potential claims from such persons. We approved compensation to our impacted employees, directors, consultants, and other service providers to mitigate potential claims related to the communicated grants of option awards, if any, an impacted individual could argue that such compensation is not an adequate remedy for prior invalid option awards and, if a court were to impose a greater remedy, our financial exposure could be greater and have a material adverse effect on our business and results of operations. The foregoing could also result in tax withholding, employment taxes or other tax liabilities, including penalties and interest, all of which could have a material adverse effect on our business, financial condition and results of operations.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

At June 30, 2018, we had 75 full-time employees. As our sales and marketing strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our product will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and, accordingly, may not achieve our research, sales and marketing goals, which would have a material adverse effect on our business, financial condition, and results of operations.

We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA and Federal Trade Commission. For example, promotional communications and endorsements on social media that, among other things, promote our products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label uses"), do not contain a fair balance of information about risks associated with using our products, make comparative or other claims about our products that are not supported by sufficient evidence, and/or do not contain required disclosures could result in an enforcement actions against us. In addition, adverse events, product complaints, off-label usage by physicians, unapproved marketing or other unintended messages posted on social media could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. Further, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill, which would have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Regulatory Approval and our Industry

Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA, EMA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time consuming, complex and uncertain. FDA and EMA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacture (including suppliers) and testing;
- pre-clinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Our current products are subject to extensive regulation by the FDA and non-U.S. regulatory agencies. Further, all of our potential products and improvements of our current products will be subject to extensive

regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials, and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The FDA can also refuse to clear or approve pending applications. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition, and results of operations.

Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.

Medical devices regulated by the FDA are subject to "general controls" which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMPs under the Quality System Regulations, or QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to premarket approval, or PMA. None of our current products are Class III devices, but future products could be, which would subject them to the PMA process.

Many medical devices, such as medical lasers, are also regulated by the FDA as "electronic products." In general, manufacturers and marketers of "electronic products" are subject to certain FDA regulatory requirements intended to ensure the radiological safety of the products. These requirements include, but are not limited to, filing certain reports with the FDA about the products and defects/safety issues related to the products as well as complying with radiological performance standards.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. Such reviews and investigations may result in the civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations.

Product clearances and approvals can often be denied or significantly delayed.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data.

The PMA process typically is more costly, lengthy and stringent than the 510(k) process. Unlike a 510(k) review which determines "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the U.S. and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements or additional 510(k) premarket clearances to market modifications to our existing products. The FDA requires device manufacturers to make and document a determination of whether a modification requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not approve our current or future PMA applications or supplements or clear our 510(k) applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Although we have obtained regulatory clearance for our products in the U.S. and certain non-U.S. jurisdictions, they will remain subject to extensive regulatory scrutiny.

Although our products have obtained regulatory clearance in the U.S. and certain non-U.S. jurisdictions, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of

safety, effectiveness, and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable non-U.S. regulatory authorities.

Our manufacturing facility is required to comply with extensive requirements imposed by the FDA, EMA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to the QSR or similar regulations set by foreign regulatory authorities. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510(k) application. Accordingly, we continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted or to the conditions of approval, or contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. However, many physicians use our products for off-label purposes and are allowed to do so. For certain changes to a cleared product, including certain changes to product labeling, the holder of a cleared 510(k) application may be required to submit a new application and obtain clearance.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- subject our facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication, or correspondence;
- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- impose civil or criminal penalties;
- suspend or withdraw regulatory clearances or approvals;
- refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
- seize or detain products; or
- require a product recall.

In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, which would have a material adverse effect on our business, financial condition, and results of operations.

Our products may be subject to recalls after receiving FDA, EMA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA, EMA and similar foreign governmental authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions, or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business. The EMA may also order us to reimburse parties affected by the recall of our products.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA, EMA, or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints that we have received rose to a level required to be reported to the FDA. We are currently evaluating and responding to the FDA's inspectional observations. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA, EMA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with the FDA's Quality System Regulation or any applicable state equivalent, our operations could be interrupted and our potential product sales and operating results could suffer.

We are required to comply with the FDA's QSR, which delineates the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. Our facilities have been inspected by the FDA and other regulatory authorities, and we anticipate that we and certain of our third-party component suppliers will be subject to additional future inspections. If our facilities are found to be in non-compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, FDA could take legal or regulatory enforcement

actions against us and/or our products, including but not limited to the cessation of sales or the recall of distributed products, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. We are also subject to periodic inspections by the FDA, other governmental regulatory agencies, as well as certain third-party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations, or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend, prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and/or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product.

Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in the products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

If any of our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, or MDR regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. The most frequent complication reported to us as a result of post-market surveillance is clinically non-significant vessel perforation. If we fail to report these events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action,

whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require our time and capital, distract management from operating our business, and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed. The ACA has made significant changes to the way healthcare is financed by both federal and state governments and private insurers, and has directly impacted the medical device industry. Among other provisions that may affect our business, including provisions meant contain healthcare costs, improve quality and/or expand access, the ACA implemented, with limited exceptions, a deductible excise tax of 2.3% on sales of medical devices by entities, including us, which manufacture or import certain medical devices offered for sale in the U.S., including many of our products. The tax was to become effective January 1, 2013, but is currently suspended until January 1, 2020. Revenue from many of our products will be subject to that excise tax.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share. Congress may consider additional legislation to repeal or repeal and replace all or certain elements of the ACA, including the medical device excise tax. We continue to evaluate the impact of the ACA and its possible repeal or replacement on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Congress and the

Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could have a material adverse effect on our business, financial condition, and results of operations.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business.

Our products are purchased principally by catheterization laboratories, which typically bill various third-party payors, including governmental programs, such as Medicare and Medicaid, private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our customers to obtain reimbursement for procedures that are performed using our products from government and private third-party payors is critical to our success. The availability of coverage and reimbursement for procedures performed using our products affects which products customers purchase and the prices they are willing to pay to us.

Reimbursement varies based on country, geographical location and third-party payor and can significantly influence the acceptance of new products and services. Third-party payors may view some procedures performed using our products as experimental and may not provide coverage. Third-party payors may not cover and reimburse our customers for certain procedures performed using our products in whole or in part in the future, or payment rates may not be adequate, or both. Further, coverage and reimbursement by third-party payors to our customers is also related to billing codes to describe procedures performed using our products. Hospitals and physicians use several billing codes to bill for such procedures. Third-party payors may not continue to recognize the CPT codes available for use by our customers.

Reimbursement rates are unpredictable, and we cannot project how our business may be affected by future legislative and regulatory developments. Future legislation or regulation, or changing payment methodologies, may have a material adverse effect on our business, financial condition, and results of operations, and reimbursement may not be adequate for all customers. From time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. Because the cost of our products generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our products. For example, in July 2013, the CMS proposed reimbursement changes that would have decreased reimbursement for procedures in an outpatient based facility. Although CMS chose not to implement those changes in 2013, we cannot assure you that CMS will not take similar actions in the future.

After we develop new products or seek to market our products for new approved or cleared indications, we may find limited demand for the product unless government and private third-party payors provide adequate coverage and reimbursement to our customers. Even with reimbursement approval and coverage by government and private payors, providers submitting reimbursement claims may face delay in payment if there is confusion by providers regarding the appropriate codes to use in seeking reimbursement. Such delays may create an unfavorable impression within the marketplace regarding the level of reimbursement or coverage available for our products.

Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the U.S., there have been and we expect there will continue to be legislative and regulatory proposals to change the healthcare system, such as the potential repeal of the ACA, some of which could significantly affect our business. It is uncertain what impact the current U.S. presidential administration will have on health care spending including a campaign promise to repeal the ACA. If enacted and implemented, any measures to restrict health care spending could result in decreased revenue from our products and decreased potential returns from our research and development initiatives. Other legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures performed using our products or denies coverage for those procedures could have a material adverse effect on our business, financial condition, and results of operations.

Modifications to our products may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing our products until clearances are obtained.

Modifications to our products may require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA will review and can disagree with a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We may make modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions.

Our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services,

as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of business conduct and ethics that will become effective upon the completion of this offering, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations.

Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our on our business, financial condition, and results of operations. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations, which could have a material adverse effect on our business, financial condition, and results of operations.

Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation of our cleared devices and any future cleared or approved devices. Our current and future arrangements with providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our cleared devices.

Restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or

indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity for purposes of HIPAA, and we believe that we generally do not conduct our business in a manner that would cause us to be a business associate under HIPAA;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require medical device manufacturers to report information related to payments and other transfers

of value to physicians and other healthcare providers or marketing expenditures. In addition, we may be subject to state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occurs, it could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology may be adversely affected.

As with other medical device companies, our ability to maintain and solidify a proprietary position for our products will depend upon our success in obtaining effective patent claims that cover such products, their manufacturing processes and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, we may not be able to obtain issued claims covering DABRA and Pharos, as well as other technologies that are important to our business, which are sufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to DABRA and Pharos could have a material adverse effect on our business, financial condition, and results of operations.

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may

breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, and the like, although we are unaware of any such defects that we believe are of material importance. If we or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, if any patents are issued in the future, they may not provide us with any competitive advantages, or may be successfully challenged by third parties. Agreement terms that address non-competition are difficult to enforce in many jurisdictions and may not be enforceable in any particular case. To the extent that our intellectual property and other proprietary rights are not adequately protected, third parties might gain access to our proprietary information, develop and market products or services similar to ours, or use trademarks similar to ours, each of which could materially harm our business. Existing United States federal and state intellectual property laws offer only limited protection. Moreover, the laws of other countries in which we now, or may in the future, conduct operations or contract for services may afford little or no effective protection of our intellectual property. The failure to adequately protect our intellectual property and other proprietary rights could materially harm our business.

The strength of patent rights involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own may fail to result in issued patents in the United States or foreign countries with claims that cover our products or services. Even if patents do successfully issue from the patent applications that we own, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products and services. Furthermore, even if they are unchallenged, our patents may not adequately protect our products and services, provide exclusivity for our products and services, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products and services is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products and services.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years

after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our products and services that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and products would be adversely affected.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our products or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether DABRA and Pharos will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims

being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of DABRA and Pharos. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us, which would have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the U.S. over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, and results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the U.S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our products or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Issued patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our patents before administrative bodies in the U.S. or abroad, even

outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our products, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect our proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants, and other third parties, and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our patents, trade secrets or other intellectual property. If we

fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

We may become involved in intellectual property litigation either due to claims by others that we are infringing their intellectual property rights or due to our own assertions that others are infringing upon our intellectual property rights.

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patent infringement and intellectual property rights. Our competitors hold a significant number of patents relating to medical laser technology. From time to time, we may commence litigation to enforce our intellectual property rights. An adverse decision in these actions or in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively impact our business, financial condition and results of operations.

Monitoring unauthorized use of our intellectual property is difficult and costly. Unauthorized use of our intellectual property may have occurred or may occur in the future. Although we have taken steps to minimize the risk of this occurring, any such failure to identify unauthorized use and otherwise adequately protect our intellectual property would adversely affect our business. Moreover, if we are required to commence litigation, whether as a plaintiff or defendant, not only will this be time-consuming, but we will also be forced to incur significant costs and divert our attention and efforts of our employees, which could, in turn, result in lower revenue and higher expenses.

We cannot provide assurance that our products or methods do not infringe the patents or other intellectual property rights of third parties. Additionally, if our business is successful, the possibility may increase that others will assert infringement claims against us.

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of a patent litigation action is often uncertain. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for medical lasers and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. In certain situations, we may determine that it is in our best interests or their best interests to voluntarily challenge a party's products or patents in litigation or other proceedings, including patent interferences or re-examinations. As a result, we may become involved in unwanted litigation that could be costly, result in diversion of management's attention, require us to pay damages and force us to discontinue selling our products.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and

proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. We cannot be certain that we will successfully defend against allegations of infringement of patents and intellectual property rights of others. In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the other party's patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the other party's patents or violate the terms of a license to which we are a party, we could be required to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all, and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid violating or infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of our products.

The medical devices industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and any potential future collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any licensee to alter our development or commercial strategies, obtain licenses, or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Third parties may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our products. In this case, the holders of such patents may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we

may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

For example, in December of 2017, we were contacted by a third party suggesting that we should consider licensing three U.S. patents directed to the treatment of vitiligo, U.S. Pat. No. 6,979,327 ("'327 patent"), U.S. Pat. No. 7,261,729 ("'729 patent"), and U.S. Pat. No. 8,387,621 ("'621 patent"). In addition, we were also previously contacted in 2006 by the same third party suggesting that we should consider licensing the '327 patent as well as the then pending application that became the '729 patent. We believe that we will be meritorious if a claim of infringement of the '327 patent, the '729 patent, or the '621 patent is asserted against us in a legal proceeding. However, although we believe that we do not infringe the claims of the '327 patent, the '729 patent, or the '621 patent, nor do we believe that we need a license to the '327 patent, the '729 patent, or the '621 patent in order to freely commercialize our products, there is a possibility that a suit claiming infringement of the '327 patent, the '729 patent, or the '621 patent will be brought against us, and we cannot assure that a court or an administrative agency will agree with our assessment with regard to non-infringement of the '327 patent, the '729 patent, or the '621 patent. If it was necessary to obtain a license to the '327 patent, the '729 patent, or the '621 patent and a license was not available on commercially reasonable terms or available at all, that could affect our ability to commercialize our products and materially and adversely affect our business.

If a third party commences a patent infringement action against us it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing products. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our products, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and scientific advisors are currently or were previously employed at universities or healthcare companies, including competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we have been and may in the future become subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. For example, in 2018, we received letters from a competitor concerning one of their former employees who is currently working for us. The letters allege, among other things, that the employee is in violation of the employee's continuing obligations to the employee's prior employer. While we dispute the validity of the claims and would vigorously defend against them and assert appropriate defenses, litigation may be necessary to defend against these claims. If we fail in defending any such claims, it could have a material adverse effect on our business, financial condition, and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may

be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of the patents that we may own or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Reliance on Third Parties

We depend on third-party suppliers for key components and sub-assemblies used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate components and sub-assemblies could harm our business.

We may encounter unforeseen situations that would result in delays or shortfalls in manufacturing. Key components and sub-assemblies of DABRA and Pharos are currently provided by a limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies. For example, we rely on a limited number of suppliers for the Thyratron used to manufacture our lasers. If we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our costs, result in manufacturing delays, and cause delays in the delivery of our products. We may also experience a delay in completing validation and verification testing or sterility audits for controlled-environment rooms at our facility.

We also depend on limited source suppliers for some of our product components and sub-assemblies, and if any of those suppliers are unable or unwilling to produce these components or sub-assemblies or supply them in the quantities that we need, and at acceptable prices, we would experience manufacturing delays and may not be able to deliver our products on a timely or cost-effective basis to our customers, or at all, which could reduce our product sales, increase our costs, and harm our business. While we believe that we could obtain replacement components from alternative suppliers, we may be unable to do so. Losing any of these suppliers could cause a disruption in our production. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. Establishing additional or replacement suppliers for these materials may take significant time, as certain of these suppliers must be approved by regulatory authorities, which could disrupt our production. As a result, we could experience significant delays in manufacturing and delivering our products to customers. We cannot assure you we can continue obtaining required materials, components, and sub-assemblies that are in short supply within the time frames we require at an affordable cost, if at all. If we cannot secure on a timely basis sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then manufacturing our products may be disrupted, which could increase our costs, prevent or impair our development or commercialization efforts, and have a material adverse effect on our business, financial condition, and results of operations.

We and our component suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we must register with the FDA and non-U.S. regulatory agencies, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our component suppliers comply or can continue to comply with all regulatory requirements. The failure by us or one of our component suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, with a component supplier, until a new supplier has been identified and evaluated. Our or any of our component supplier’s failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we can locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

In the European Union, we must maintain certain International Organization for Standardization, or ISO, certifications to sell our products and must undergo periodic inspections by notified bodies, including the British Standards Institution, to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, it could have a material adverse effect on our business, financial condition, and results of operations.

We may form or seek strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits or costs of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our sales and marketing efforts with respect to our products and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our products. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our products could delay the commercialization of our products in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Risks Related to This Offering and Ownership of Our Common Stock

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future products, which will change from time to time;
- the cost of manufacturing our current and any future products, which may vary depending on FDA and EMA guidelines and requirements, the quantity of production and the terms of our agreements with suppliers;
- the degree and rate of market acceptance for DABRA and Pharos, including the ability of our customers to receive adequate reimbursement for procedures performed using our products;
- expenditures that we will or may incur to acquire or develop additional products and technologies;
- competition from existing and potential future products that compete with our products, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the level of demand for our current and future products, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products, and existing and potential future products that compete with our products;
- our ability to commercialize additional products, if approved, inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing, or other arrangements;
- our ability to adequately support future growth;

- potential unforeseen business disruptions that increase our costs or expenses;
- changes in FDA regulations and comparable foreign regulations;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, after the closing of this offering, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

From time to time, we may also enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend in part on any potential future license and collaboration agreements and sales of our products. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

The price of our stock may be volatile, and you could lose all or part of your investment. Further, we do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering there has been no public market for shares of our common stock. Although we have applied to have our common stock listed on the New York Stock Exchange, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk factors" section and elsewhere in this prospectus, these factors include:

- our failure to increase the sales of our products, specifically DABRA;

- the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers;
- unanticipated serious safety concerns related to the use of our products;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our target markets;
- actual or anticipated variations in quarterly operating results;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including stockholder litigation or litigation related to intellectual property;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products or maintain regulatory approval for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;
- ineffectiveness of our internal controls;

- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

We do not intend to pay dividends on our common stock so any returns will be limited to increases, if any, in our stock's value.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2017, we had net operating loss, or NOL, carryforwards of approximately $7.2 million for federal income tax purposes, and $7.0 million for state income tax purposes. These federal and state NOL carryforwards begin expiring in 2029. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, including this offering, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the Tax Cuts and Jobs Act of 2017, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely and the deductibility of such federal NOLs is limited.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on December 22, 2017, President Trump signed tax legislation into law, commonly referred to as the Tax Cuts and Jobs Act of 2017, that

contains many significant changes to the U.S. tax laws, the consequences of which have not yet been fully determined. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses contained in the Tax Cuts and Jobs Act of 2017 or other tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items could have a material adverse effect on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax legislation. The impact of this tax legislation on holders of our common stock is also uncertain and could be adverse. We urge our stockholders and investors to consult with our legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately 62% of the outstanding shares of our common stock as of July 13, 2018, and, upon the closing of this offering, that same group will hold approximately % of our outstanding shares of common stock (assuming no exercise of the underwriters' option to purchase additional shares). In addition, as of July 13, 2018, our officers and directors held (i) options to purchase an aggregate of 1,221,000 shares of our common stock at exercise prices of $28.94 per share; and (ii) 858,926 restricted stock units, which would give our officers and directors ownership of approximately % of our outstanding common stock following this offering if such awards are fully vested and are exercised in full (assuming no exercise of the underwriters' option to purchase additional shares). Therefore, even after this offering, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders, which could have a material adverse effect on our business, financial condition, and results of operations.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the New York Stock Exchange to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than anticipated or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. Further, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since our inception, but will own only approximately % of the shares of common stock outstanding after giving effect to this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering. To the extent outstanding options are exercised and outstanding restricted stock units vest, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

Future sales and issuances of a substantial number of shares of our common stock or rights to purchase common stock by our stockholders in the public market could result in additional dilution of the percentage ownership of our stockholders and cause our stock price to fall.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on 7,944,251 shares of common stock outstanding at March 31, 2018, upon the closing of this offering we will have outstanding a total of shares of common stock, assuming no exercise of outstanding options or vesting of outstanding restricted stock units after March 31, 2018. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. The underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

The lock-up agreements pertaining to this offering will expire after 180 days from the date of this prospectus. Subject to certain limitations, approximately shares will become eligible for sale upon expiration of the lock-ups in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, Rule 144 and Rule 701 under the Securities Act, and our insider trading policy. Shares issued or issuable upon the exercise of options vested as of the expiration of the lock-up period will be eligible for sale at that time, as well as shares to be issued upon settlement of outstanding restricted stock units that vest following the completion of this offering. Moreover, pursuant to our 2018 Plan, our Board is authorized to grant equity incentive awards representing up to an aggregate of shares of our common stock to our employees, directors and consultants. The 2018 Plan includes an annual increase in the number of shares available for future grant each year pursuant to the "evergreen" provision of our 2018 Plan. Additionally, pursuant to our ESPP a total of shares are available for sale under our ESPP. The ESPP also includes an annual increase in the number of shares available for sale under our ESPP each year pursuant to the "evergreen" provision of our ESPP. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline.

Further, we expect that significant additional capital may be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock, including shares of common stock sold in this offering.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering for the expansion of our direct sales force and marketing of our products, to support clinical studies for new products and product enhancements including for expanded indications, and to support other research and development activities, working capital, and general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our current management and may adversely affect the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon completion of this offering contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- our board of directors will be divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) or a majority vote of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 $^{2}/_{3}$% of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the issuance of preferred stock and management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt;
- the ability of our board of directors, by majority vote, to amend our amended and restated bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our amended and restated bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, because we are now incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a

court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

SPECIAL NOTES REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the section captioned "Prospectus summary," "Risk factors," "Management's discussion and analysis of financial condition and results of operations," "Business," and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these terms.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our plans to obtain funding for our operations, including funding necessary to develop, manufacture and commercialize our products;
- the size and growth of the markets for our products;
- the rate and degree of market acceptance of our products;
- our ability to seek and obtain approvals for new indications for our products;
- our commercialization, marketing, and manufacturing capabilities and strategy;
- our ability to compete with companies currently producing alternative treatment methods;
- our expectations regarding the ease of administration associated with our products;
- pricing and reimbursement for procedures performed using our products;
- our plans to research, develop and commercialize our products and any other approved product;
- our ability to establish the potential immunotherapeutic effects of DABRA with a study or registry;
- the cost, timing and outcomes of any potential litigation involving our products;
- our expectation that our capital resources will be sufficient to fund our operations for our operations for at least the next 12 months;
- regulatory developments in the U.S. and in non-U.S. countries;
- the performance of third parties in connection with the development of our products, including third-party suppliers;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our ability to retain key scientific or management personnel;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology;
- the terms and conditions of licenses granted to us and our ability to license additional intellectual property related to our products, as appropriate;

- our expectations regarding our ability to obtain and maintain intellectual property protection for our products;
- potential claims related to our intellectual property;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our ability to develop innovative new products;
- our financial performance; and
- our anticipated use of the net proceeds from this offering.

In addition, you should refer to the "Risk factors" section of this prospectus for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus forms a part with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our general expectations and market position, market opportunity, and market size, is based on information from various third-party industry and research sources, on assumptions that we have made based on that data and other similar sources, and on our knowledge of the markets for our services. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

In addition, industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section captioned “Risk factors” and elsewhere in this prospectus. These and other factors could cause our actual results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of common stock in this offering will be approximately $ million at an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds will be approximately $ million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) our net proceeds by $ million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $ million, assuming the assumed initial public offering price stays the same.

We intend to use the net proceeds of this offering as follows:

- approximately $ million for the expansion of our direct sales force and marketing of our products;
- approximately $ million to support clinical studies for new products and product enhancements including for expanded indications; and
- the balance of the proceeds may be used to support other research and development activities, working capital, and general corporate purposes.

We may also use a portion of the net proceeds of this offering for acquisitions to bolster our product offerings. We have not entered into any agreements or commitments with respect to any specific acquisitions and have no understandings or agreements with respect to any such acquisition or investment at this time.

Due to the uncertainties inherent in the product development and commercialization process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. The amount and timing of our actual expenditures will depend upon numerous factors. As a result, our management will have broad discretion over the use of the net proceeds from this offering.

We are undertaking this offering in order to access the public capital markets and to increase our liquidity. At March 31, 2018, we had cash and cash equivalents of $7.1 million. Based on our current plans, we believe that our existing cash and cash equivalents, which includes private placement funds raised in the second quarter of 2018, and the net proceeds raised from this offering will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Pending use of the proceeds as described above, we intend to invest the proceeds in a variety of capital preservation investments, including interest-bearing, investment-grade instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions, the terms of any future credit agreements and other factors that our board of directors may deem relevant. See the section entitled “Material U.S. federal income tax consequences to non-U.S. holders of the ownership and disposition of our common stock” for a discussion of certain withholding and other tax considerations with respect to dividends paid to non-U.S. holders (as defined therein) of our common stock.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, debt obligations, and capitalization as of March 31, 2018:

- on an actual basis;
- on a pro forma basis to reflect the issuance of 260,000 shares of common stock in exchange for $6.5 million received in proceeds in connection with our private placement subsequent to the historical periods presented; and
- on a pro forma as adjusted basis to give effect to the issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of March 31, 2018		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 7,083	$ 13,583	$
Capitalization:			
Equipment financing	53	53	
Stockholders' (deficit) equity:			
Common stock, no par value: 10,000,000 shares authorized, actual and pro forma; shares authorized, pro forma as adjusted; 7,944,251 shares issued and outstanding, actual; 8,204,251 shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted	—	—	
Additional paid-in capital	23,175	29,675	
Accumulated deficit	(32,082)	(32,082)	
Total stockholders' deficit	(8,907)	(2,407)	
Total capitalization	$ (8,854)	$ (2,354)	$

(1) Pro forma amounts reflect the issuance of 260,000 shares of common stock in exchange for $6.5 million received in proceeds in connection with our private placement financing subsequent to the historical periods presented.

(2) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing pro forma as adjusted information is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and the related notes appearing elsewhere in this prospectus and the "Selected financial data"

and “Management’s discussion and analysis of financial condition and results of operations” sections of this prospectus.

The foregoing discussion and table is based on 7,944,251 shares of our common stock outstanding as of March 31, 2018 and excludes:

- 1,892,000 shares of common stock issuable upon exercise of outstanding options that were issued following March 31, 2018 at an exercise price of $28.94 per share under our Compensation Plan;
- 1,337,722 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units that were issued following March 31, 2018 under our Compensation Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of:
  - 70,278 shares of common stock reserved for future issuance under our Compensation Plan as of July 13, 2018, which shares will be added to the shares to be reserved under our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for future issuance under our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for future issuance under our ESPP, which will become effective upon the completion of this offering; and
  - any shares that become available under our 2018 Plan and ESPP, pursuant to provisions that automatically increase the reserves under such plans each year.

DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of our common stock in this initial public offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after completion of this offering.

Our historical net tangible book deficit as of March 31, 2018 was approximately $8.9 million, or $(1.12) per share of common stock. Our historical net tangible book deficit is the amount of our total tangible assets less our total liabilities. Historical net tangible book deficit per share is our historical net tangible book deficit divided by the number of shares of common stock outstanding as of March 31, 2018.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value (deficit) at March 31, 2018 would have been $ million, or $ per share of common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value (deficit) of $ per share to existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value (deficit) of $ per share to new investors.

The following table illustrates this dilution:

Assumed initial public offering price per share		$
Historical net tangible book deficit per share as of March 31, 2018	$(1.12)	
Increase (decrease) in pro forma as adjusted net tangible book deficit per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after giving effect to this offering	$	
Dilution in pro forma as adjusted net tangible book value (deficit) per share to investors purchasing common stock in this offering		$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book deficit per share to new investors by $, and would increase (decrease) dilution per share to new investors in this offering by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. In addition, to the extent any outstanding options to purchase common stock are exercised or any outstanding restricted stock units vest, new investors would experience further dilution. If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value per share of our common stock after giving effect to this offering would be approximately $ per share, and the dilution in pro forma as adjusted net tangible book value per share to investors in this offering would be approximately $ per share of common stock.

The following table summarizes, on an pro forma as adjusted basis as of March 31, 2018, the total number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid to us by existing stockholders and by new investors purchasing shares of common stock in this offering at the initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					
Total		100%	$	100%	

Except as otherwise indicated, the above discussion and tables assumes no exercise by the underwriters of their option to purchase up to additional shares from us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) each of the total consideration paid by new investors and total consideration paid by all stockholders by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) each of the total consideration paid by new investors and total consideration paid by all stockholders by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. In addition, to the extent any outstanding options to purchase common stock are exercised or any outstanding restricted stock units have vested, new investors will experience further dilution.

If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding after this offering.

The foregoing discussion and tables are based on 7,944,251 shares of our common stock outstanding as of March 31, 2018 and excludes:

- 1,892,000 shares of common stock issuable upon exercise of outstanding options that were issued following March 31, 2018 at an exercise price of $28.94 per share under our Compensation Plan;
- 1,337,722 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units that were issued following March 31, 2018 under our Compensation Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of:
  - 70,278 shares of common stock reserved for future issuance under our Compensation Plan as of July 13, 2018, which shares will be added to the shares to be reserved under our 2018 Plan, which will become effective upon the completion of this offering;

- shares of common stock reserved for future issuance under our 2018 Plan, which will become effective upon the completion of this offering;
- shares of common stock reserved for future issuance under our ESPP, which will become effective upon the completion of this offering; and
- any shares that become available for future issuance under our 2018 Plan and ESPP, pursuant to provisions that automatically increase the reserves under such plans each year.

SELECTED FINANCIAL DATA

The following tables summarize our selected financial data for the periods and as of the dates indicated. We have derived our selected statements of operations data for the years ended December 31, 2016 and 2017, and our selected balance sheet data as of December 31, 2016 and 2017, from our audited financial statements and related notes included elsewhere in this prospectus. We have derived the statements of operations data for the three months ended March 31, 2017 and 2018 and the balance sheet data as of March 31, 2018 from our unaudited interim financial statements and related notes included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect, in the opinion of management, all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the unaudited interim financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and the results for the three months ended March 31, 2018 are not necessarily indicative of results to be expected for the full year or any other period. You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the section captioned "Management's discussion and analysis of financial condition and results of operations."

	Years Ended December 31,		Three Months Ended March 31,	
	2016	2017	2017	2018
	(in thousands, except per share data)			
Net revenue	$ 5,976	$ 5,870	$ 1,065	$ 969
Cost of revenue	3,138	4,165	602	736
Gross profit	2,838	1,705	463	233
Operating expenses				
Selling, general and administrative	5,321	14,947	1,745	2,639
Research and development	1,715	4,518	379	286
Total operating expenses	7,036	19,465	2,124	2,925
Operating loss	(4,198)	(17,760)	(1,661)	(2,692)
Other expense				
Interest expense	3	4	1	1
Total other expense	3	4	1	1
Loss before income tax expense	(4,201)	(17,764)	(1,662)	(2,693)
Income tax expense	1	1	—	—
Net loss	(4,202)	(17,765)	(1,662)	(2,693)
Basic and diluted net loss per share	$ (0.60)	$ (2.35)	$ (0.22)	$ (0.34)
Basic and diluted weighted average common shares outstanding	6,951	7,545	7,463	7,938

	As of December 31,		
	2016	2017	As of March 31, 2018
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 3,921	$ 8,237	$ 7,083
Working capital	2,598	7,409	5,925
Total assets	5,842	11,269	10,606
Equipment financing	107	63	53
Accumulated deficit	(11,624)	(29,389)	(32,082)
Total stockholders' deficit	$ (380)	$ (7,615)	$ (8,907)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Special note regarding forward-looking statements" and "Risk factors" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of the DABRA laser system and disposable catheter, together referred to as DABRA, in the United States. Following the temporary placement period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements, or Usage Agreements, with each customer. As of June 30, 2018, we had a U.S. installed base of 31 DABRA laser systems, eight of which have signed Usage Agreements with us, and the remainder of which are temporarily placed for use in demonstrations, trials, or training. DABRA is cleared by the U.S. Food and Drug Administration, or FDA, as a tool for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease, which includes peripheral artery disease, or PAD, which commonly occurs in the legs. We intend to pursue additional uses for DABRA, including seeking regulatory clearance for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other venous and arterial occlusions, or blockages in the veins or arteries. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA is our minimally-invasive excimer laser and disposable catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging. Recent analysis suggests that 17.6 million people in the U.S. suffer from PAD. However, only 20-30% of PAD patients are actively being treated. We anticipate revenue from this recently

commercialized business segment to grow over the near term. Our sales strategy includes either selling DABRA with a transfer in title or placing it in high-volume practices for a nominal monthly fee while we retain title. We sell extended warranties for our lasers that have been purchased. Each vascular procedure requires the one-time use of one of our proprietary catheters which we expect to be the primary source of revenue for the vascular segment. Therefore, under both the sale and monthly fee options, we anticipate recurring revenue in catheter sales for each laser in operation. We currently use our internal sales force to target the U.S. market and we utilize the current retail price distributors outside the U.S. The current retail price of the DABRA laser is approximately $70,000 and of a DABRA catheter is $1,200.

Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. We have also received clearance to market Pharos from the European Medicines Agency, or EMA, China Food and Drug Administration, or CFDA, and South Korea Ministry of Drug Safety, or KFDA in the applicable jurisdictions. Pharos was commercialized in 2004 and we have shipped over 1,000 systems to customers globally. Pharos is in use in nearly every U.S. state and in over 20 markets including several non-U.S. countries. While we have entered into monthly fee arrangements, our primary strategy is to sell Pharos. We recognize additional recurring revenue from the sale of extended warranties for Pharos. We do not anticipate significant organic revenue growth in the near term from this mature product line. The current retail price of Pharos is approximately $70,000.

We incurred net losses of $4.2 million, $17.8 million, and $2.7 million for the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018, respectively, and had an accumulated deficit of $32.1 million as of March 31, 2018. As of March 31, 2018, we had available cash and cash equivalents of approximately $7.1 million and had current liabilities of approximately $2.8 million and long-term liabilities of approximately $16.7 million, which included a $15.9 million stock-based compensation liability. As of March 31, 2018, we had no preferred stock outstanding and no indebtedness through commercial loans, other than the equipment financings of $0.1 million. Since inception, we have financed our operations primarily through sales of our products and services and, to a lesser extent, private placements of our common stock and debt financing arrangements. We expect to continue to incur net losses for the near term as we commercialize our products in the U.S., including building our sales and marketing organization and expanding our manufacturing facilities, continuing research and development efforts, and seeking regulatory clearance for new products and product enhancements, including new indications, both in the U.S. and in select non-U.S. markets. We will need additional funding to pay expenses relating to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, financial condition, and results of operations.

Components of our Results of Operations

Net revenue

Product sales consist of the sale of DABRA and Pharos, the sale of catheters for use in the DABRA laser and the sale of consumables and replacement parts.

Services and other revenues consists primarily of sales of extended warranties which is recognized over the contract period and billable services, including repair activity, which is recognized when the service is provided. It also includes income from the rental of our lasers.

We currently use our internal sales force to target the U.S. market, and we utilize distributors outside the U.S. in markets where we have received regulatory approval. We will continue to seek regulatory approvals for our products in additional strategic markets.

Cost of revenue and gross margin

Cost of revenue for product sales consists primarily of costs of components for use in our products, the materials and labor that are used to produce our products, and the manufacturing overhead that directly support production.

Cost of revenue for services and other includes the cost of maintaining and serving the warranties on our products.

We expect cost of revenue to increase to the extent our total revenue grows.

We calculate gross margin as gross profit divided by total net revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of direct materials, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to increase over the long term as our production volume increases and certain costs remain fixed. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

Research and development, or R&D, expenses consist of applicable personnel, consulting, materials and clinical trial expenses. R&D expenses include:

- certain employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;
- cost of outside consultants who assist with technology development, regulatory affairs, clinical affairs and quality assurance;
- cost of clinical studies to support new products and product enhancements, including expanded indications; and
- supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. In the future, we expect R&D expenses to increase as we continue to develop new products, enhance existing products and technologies and perform activities related to obtaining additional regulatory approval. However, we expect R&D expenses as a percentage of total revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, benefits, travel expense, sales commissions and stock-based compensation expense. Other SG&A expenses include promotional activities, marketing, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses, allocated facilities-related expenses and shipping and handling costs. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing DABRA in both domestic and international markets. We also expect increased costs due to the additional legal, accounting, insurance

and other expenses associated with becoming a public company. As a result, we expect SG&A expenses to increase as a percentage of total net revenue for the foreseeable future.

Results of Operations

Comparison of the Three Months Ended March 31, 2017 and 2018

The following table shows our results of operations for the three months ended March 31, 2017 and 2018 (in thousands):

	Three months ended March 31,		Change	
	2017	2018	$	%
Statements of operations data:				
Net revenue				
Product sales	$ 405	$ 235	$ (170)	(42%)
Service and other	660	734	74	11%
Total net revenue	1,065	969	(96)	(9%)
Cost of revenue				
Product	321	342	21	7%
Service and other	281	394	113	40%
Total cost of revenue	602	736	134	22%
Gross profit	463	233	(230)	(50%)
Operating expenses:				
Selling, general and administrative	1,745	2,639	894	51%
Research and development	379	286	(93)	(25%)
Total operating expenses	2,124	2,925	801	38%
Operating loss	(1,661)	(2,692)	(1,031)	62%
Interest expense	1	1	—	0%
Loss before income taxes	(1,662)	(2,693)	(1,031)	62%
Income tax expense	—	—	—	0%
Net loss	$ (1,662)	$ (2,693)	$ (1,031)	62%

Comparison of the Three Months Ended March 31, 2017 and 2018—By reportable segments

We organize our business into two operating segments based on the product specialties: the vascular segment and the dermatology segment. In deciding how to allocate resources and assess performance, we regularly evaluate the net revenue and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to us and not specific to a particular segment; therefore, these amounts are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 11 to the interim condensed financial statements appearing elsewhere in this prospectus.

Net revenue

The following table shows our net revenue from our two segments for the three months ended March 31, 2017 and 2018 (in thousands):

	Three months ended March 31,		Change	
	2017	2018	$	%
Vascular	—	90	90	*
Dermatology	$ 1,065	$ 879	$(186)	(17%)
Total net revenue	$ 1,065	$ 969	$ (96)	(9%)

* Not applicable

Vascular

DABRA was introduced to the market in mid-2017, therefore there was zero revenue for the three months ended March 31, 2017 attributable to the vascular segment. Net revenue of $0.1 million for the three months ended March 31, 2018, was predominantly from the sale of catheters.

Dermatology

Net revenue was $1.1 million and $0.9 million for three months ended March 31, 2017 and 2018, respectively. The decrease of approximately $0.2 million was due primarily to a decrease of $0.3 million in direct unit product sales as a result of us devoting more of our sales resources in 2018 to commercializing the DABRA laser aggregated in our vascular segment, partially offset by an increase of $0.1 million in income from the rental of our lasers. We anticipate hiring additional sales resources in the dermatology segment devoted to addressing direct unit product sales.

Cost of revenue

The following table shows our cost of revenue from our two segments for the three months ended March 31, 2017 and 2018 (in thousands):

	Three months ended March 31,		Change	
	2017	2018	$	%
Vascular	$ —	$ 251	$ 251	*
Dermatology	602	485	(117)	(20%)
Total cost of revenues	$ 602	$ 736	$ 134	22%

* Not applicable

Vascular

DABRA was introduced to the market in mid-2017, therefore there was zero cost of revenue for the three months ended March 31, 2017, attributable to the vascular segment. Cost of revenue of $0.3 million for the three months ended March 31, 2018, was predominantly from catheter shipments.

Dermatology

Cost of revenue was $0.6 million and $0.5 million for the three months ended March 31, 2017 and 2018, respectively. The decrease of $0.1 million was primarily due to a $0.2 million decrease in labor, materials and overhead due to the reduced number of product shipments partially offset by an increase in

warranty costs and depreciation of $0.1 million due to an increase in the number of leased machines under warranty agreements.

Gross profit

The following table shows our gross profit from our two segments for the three months ended March 31, 2017 and 2018 (in thousands):

	Three months ended March 31,		Change	
	2017	2018	$	%
Vascular	$ —	$ (161)	$(161)	*
Dermatology	463	394	(69)	(15%)
Total gross profit	$ 463	$ 233	$(230)	(50%)

* Not applicable

Vascular

DABRA was introduced to the market in mid-2017, therefore there was zero gross margin for the three months ended March 31, 2017. For the three months ended March 31, 2018, our costs for labor, material and overhead exceeded our revenue due to us staffing ahead of customer adoption and us providing evaluation catheters during this phase of product launch. We expect our margins to improve as our customers exhaust their evaluation supplies and purchase production catheters and as our growing sales force and marketing efforts establish a larger customer base.

Dermatology

Gross profit was $0.5 million and $0.4 million for the three months ended March 31, 2017 and 2018, respectively. The decrease of $0.1 million was primarily due to higher costs in maintaining our products under warranty contracts.

Comparison of the Three Months Ended March 31, 2017 and 2018—General

Selling, general and administrative expenses. SG&A expenses were $1.7 million and $2.6 million for the three months ended March 31, 2017 and 2018, respectively. The $0.9 million increase was primarily related to an increase of $0.4 million in personnel costs due to expanding our sales force and hiring administrative staff as we prepare to operate as a public company, $0.1 million in increased facility costs due to our expansion to a larger facility, $0.1 million in legal and consulting fees as we prepare to operate as a public company, $0.1 million increase in provision for doubtful accounts and $0.2 million in various other administrative costs.

Research and development expenses. R&D expenses were $0.4 million and $0.3 million for the three months ended March 31, 2017 and 2018, respectively. The $0.1 million decrease was primarily due to less personnel and resources devoted to catheter research in 2018 as a result of the completion of our initial commercial product development in 2017.

Comparison of the Years Ended December 31, 2016 and 2017

The following table shows our results of operations for the years ended December 31, 2016, and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Statements of operations data:				
Net revenue				
Product sales	$ 3,817	$ 3,067	$ (750)	(20%)
Service and other	2,159	2,803	644	30%
Total net revenue	5,976	5,870	(106)	(2%)
Cost of revenue				
Product	2,289	2,854	565	25%
Service and other	849	1,311	462	54%
Total cost of revenue	3,138	4,165	1,027	33%
Gross profit	2,838	1,705	(1,133)	(40%)
Operating expenses:				
Selling, general and administrative	5,321	14,947	9,626	181%
Research and development	1,715	4,518	2,803	163%
Total operating expenses	7,036	19,465	12,429	177%
Operating loss	(4,198)	(17,760)	(13,562)	323%
Interest expense	3	4	1	33%
Loss before income taxes	(4,201)	(17,764)	(13,563)	323%
Income tax expense	1	1	—	—
Net loss	$(4,202)	$(17,765)	$(13,563)	323%

Comparison of years ended December 31, 2016 and 2017—By reportable segments

We organize our business into two operating segments based on the product specialties: the vascular segment and the dermatology segment. In deciding how to allocate resources and assess performance, we regularly evaluate the net revenue and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to us and not specific to a particular segment; therefore, these amounts are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 14 to the interim condensed financial statements appearing elsewhere in this prospectus.

Net revenue

The following table shows our net revenue from our two segments for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Vascular	—	259	259	*
Dermatology	$5,976	$5,611	$(365)	(6%)
Total net revenue	$5,976	$5,870	$(106)	(2%)

* Not applicable

Vascular

DABRA was introduced to the market in 2017 resulting in net revenue of $0.3 million for the year ended December 31, 2017, predominantly from the sale of catheters.

Dermatology

Net revenue was $6.0 million and $5.6 million for the years ended December 31, 2016 and 2017, respectively. The decrease of approximately $0.4 million was due primarily to a decrease of $1.0 million in direct unit product sales as a result of us devoting a portion of our sales resources in 2017 to commercializing the DABRA laser, aggregated in our vascular segment, partially offset by an increase of $0.3 million in service contract revenue and $0.3 million in income from the rental of our lasers.

Cost of revenue

The following table shows our cost of revenue from our two segments for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Vascular	$ —	$ 193	$ 193	*
Dermatology	3,138	3,972	834	27%
Total cost of revenues	$3,138	$4,165	$1,027	33%

* Not applicable

Vascular

DABRA was introduced to the market in 2017 resulting in cost of revenue of $0.2 million for the years ended December 31, 2017, predominantly from catheter shipments.

Dermatology

Cost of revenue was $3.1 million and $4.0 million for the years ended December 31, 2016 and 2017, respectively. The increase of $0.9 million was primarily due to a $0.6 million increase in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants, $0.4 million increase in maintenance costs due to the increased number of machines under service contracts partially offset by a decrease in direct and indirect product costs of $0.2 million due to a decrease in the number of direct product sales as a result of us devoting a portion of our sales and production resources in 2017 to commercializing the DABRA laser, aggregated in our vascular segment.

Gross profit

The following table shows our gross profit from our two segments for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Vascular	$ —	$ 66	$ 66	*
Dermatology	2,838	1,639	(1,199)	(42%)
Total gross profit	$2,838	$1,705	$(1,133)	(40%)

* Not applicable

Vascular

DABRA was introduced to the market in 2017 resulting in gross profit of $0.1 million for the years ended December 31, 2017, predominantly from catheter shipments.

Dermatology

Gross profit was $2.8 million and $1.6 million for the years ended December 31, 2016 and 2017, respectively. The decrease of $1.2 million was primarily due to a $0.6 million increase in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants, $0.5 million decrease in product sales and by $0.1 million due to increases in the cost of revenue driven by higher maintenance costs for devices under service contracts. Notes 2 and 11 to the financial statements appearing elsewhere in this prospectus more fully describe the accounting treatment for stock-based compensation awards.

Comparison of years ended December 31, 2016 and 2017—General

Selling, general and administrative expenses. SG&A expenses were $5.3 million and $14.9 million for the years ended December 31, 2016 and 2017, respectively. The $9.6 million increase is primarily related to an increase of $7.4 million in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants, $0.8 million related to increased sales personnel costs as a result of increased headcount, $0.5 million in travel and trade shows related to selling and marketing activities, $0.4 million in facility costs due to the addition of leased locations, which included a charge of $0.2 million for abandoning the lease on a facility that was consolidated and $0.5 million in professional fees, freight and various other administrative costs. Notes 2 and 11 to the interim condensed financial statements appearing elsewhere in this prospectus more fully describe the accounting treatment for stock-based compensation awards.

Research and development expenses. R&D expenses were $1.7 million and $4.5 million for the years ended December 31, 2016 and 2017, respectively. The $2.8 million increase is primarily due to an increase of $2.3 million in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants and $0.5 million due to increased personnel costs as a result of increased headcount and consulting costs related to technology development of the DABRA laser and catheters. Notes 2 and 11 to the interim condensed financial statements appearing elsewhere in this prospectus more fully describe the accounting treatment for stock-based compensation awards.

EBITDA and Adjusted EBITDA

EBITDA and Adjusted EBITDA are performance measures that provide supplemental information we believe is useful to analysts and investors to evaluate our ongoing results of operations, when considered alongside other GAAP measures. These Non-GAAP Measures exclude the financial impact of items management does not consider in assessing our ongoing operating performance, and thereby facilitate review of our operating performance on a period-to-period basis. Comparability to our results of operations to other companies may be impacted by our stock-based compensation which was classified as a liability and revalued at each reporting period with the change in fair value recorded to compensation expense in the statement of operations.

We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. Some of these limitations are that:

- EBITDA excludes certain recurring, non-cash charges such as deprecation of fixed assets and amortization of acquired intangible assets and, although these are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future; and
- Adjusted EBITDA further excludes stock-based compensation expense, which has been, and will continue to be for the foreseeable future, a significant recurring expense in our business and an important part of our compensation strategy as well as certain non-recurring items which may affect comparability of our core operations such as the loss on abandonment of facility.

In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison.

A reconciliation is for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with U.S. GAAP is included below. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business. We define Adjusted EBITDA as our GAAP net loss as adjusted to exclude depreciation, amortization, interest expense, income tax expense, stock-based compensation and loss on abandonment of facility.

The following is a reconciliation of Net loss to Adjusted EBITDA (in thousands):

	Year Ended December 31,		Three Months Ended March 31	
	2016	2017	2017	2018
	(in thousands)			
Statement of Operations Data:				
Net loss	$(4,202)	$(17,765)	$ (1,662)	$ (2,693)
Depreciation and amortization	95	218	32	96
Interest expense	3	4	1	1
Income tax expense	1	1	—	—
EBITDA	(4,103)	(17,542)	(1,629)	(2,596)
Stock-based compensation	2,300	12,706	426	524
Loss on abandonment of facility	—	212	—	—
Adjusted EBITDA	(1,803)	(4,624)	(1,203)	(2,072)

For fiscal 2016, Adjusted EBITDA was $(1.8) million compared to $(4.6) million for fiscal 2017. The decrease in Adjusted EBITDA primarily reflects lower gross profit and higher employee and consulting costs due to increased sales personnel and research and development efforts related to DABRA in fiscal 2017 compared to fiscal 2016.

For the three months ended March 31, 2017, Adjusted EBITDA was $(1.2) million compared to $(2.1) million for the three months ended March 31, 2018. The decrease in Adjusted EBITDA primarily reflects lower gross profit and higher personnel costs due to expanding our sales force and hiring

administrative staff as we prepare to operate as a public company in the first quarter of 2018 compared to the first quarter of 2017. In the first quarter of 2018 we also incurred increased facility costs due to our expansion to a larger facility and higher legal and consulting fees as we prepare to operate as a public company compared to the first quarter of 2017.

Liquidity and Capital Resources

As of March 31, 2018, we had cash and cash equivalents of $7.1 million and an accumulated deficit of $32.1 million. Our primary sources of capital have been from the sale of our products and services and, to a lesser extent, private placements of common stock and debt financing arrangements. Through March 31, 2018, we raised an aggregate of $21.0 million in proceeds from private placements of our common stock.

We believe that cash and cash equivalents as of March 31, 2018, the private placement funds raised in the second quarter of 2018, and the proceeds raised in this offering will be sufficient to fund our operations for at least the next 12 months. As we continue to commercialize DABRA, we expect our costs and expenses to increase in the future as we continue the development of a direct sales force, the expansion of our manufacturing facilities, and as we continue to make substantial expenditures on research and development, including the costs of any future clinical studies. Additionally, we expect to incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our DABRA and Pharos products, related consumables, and other products that may be approved in the U.S. and select non-U.S. markets;
- the costs and expenses of expanding our U.S. and international sales and marketing infrastructure and our manufacturing operations;
- the extent to which our excimer lasers are adopted by the physician community;
- the degree of success we experience in commercializing our excimer lasers and related consumables;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews;
- the costs and timing of developing variations of our excimer lasers, and, if necessary, obtaining FDA clearance to market such variations;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

Cash Flows

	Year ended December 31,				Three Months Ended March 31,			
	Actual		Change		Actual		Change	
	2016	2017	$	%	2017	2018	$	%
Net cash (used in) provided by:								
Operating activities	$(1,886)	$ (5,523)	$(3,637)	(193%)	$(1,699)	$(2,425)	$ (726)	(43%)
Investing activities	(210)	(547)	(337)	(160%)	(231)	(120)	(111)	(48%)
Financing activities	5,373	10,386	5,013	93%	(11)	1,391	1,402	*
Net increase (decrease) in cash and cash equivalents	$ 3,277	$ 4,316	$ 1,039	32%	$(1,941)	$(1,154)	$ 787	41%

* Not applicable

Net cash used in operating activities

During the year ended December 31, 2016, net cash used in operating activities was $1.9 million, consisting primarily of a net loss of $4.2 million and an increase in net operating assets of $0.1 million primarily related to decreases in accounts receivables, accrued expenses and inventories partially offset by increases in accounts payable and deferred revenue. These items were offset by non-cash charges of $2.4 million consisting of depreciation, stock-based compensation expense and common stock issued in exchange for services.

During the year ended December 31, 2017, net cash used in operating activities was $5.5 million, consisting primarily of a net loss of $17.8 million and an increase in net operating assets of $0.8 million, primarily related to decreases in accounts receivable, inventory and deferred revenue. These items were offset by non-cash charges of $13.1 million, consisting of depreciation, stock-based compensation expense, common stock issued in exchange for services and a loss on disposal of property and equipment.

Net cash used in operating activities was $1.7 million for the three months ended March 31, 2017. The use of cash in operating activities in the three months ended March 31, 2017, was primarily a result of a net loss of $1.7 million. Non-cash charges of $0.5 million consisting of depreciation and stock-based compensation were offset by an equal decrease in net operating assets and liabilities.

Net cash used in operating activities was $2.4 million for the three months ended March 31, 2018. The use of cash in operating activities in the three months ended March 31, 2018, was primarily a result of a net loss of $2.7 million and an increase in net operating assets of $0.2 million. These items were partially offset by non-cash charges of $0.7 million consisting of depreciation, stock-based compensation expense and provision for doubtful accounts.

Net cash used in investing activities

During the year ended December 31, 2016, net cash used in investing activities was $0.2 million consisting primarily of purchases of manufacturing equipment and selling and accounting software.

During the year ended December 31, 2017, net cash used in investing activities was $0.5 million consisting primarily of purchases of manufacturing equipment.

Net cash used in investing activities was $0.2 million for the three months ended March 31, 2017, consisting primarily of purchases of manufacturing equipment.

Net cash used in investing activities was $0.1 million for the three months ended March 31, 2018, consisting primarily of purchases of manufacturing equipment, tenant improvements and vehicles for our sales force.

Net cash (used in) provided by financing activities

During the year ended December 31, 2016, net cash provided by financing activities was $5.4 million, consisting primarily of net proceeds of $5.3 million from the issuance of common stock related to a private placement financing and $0.1 million in equipment financing proceeds.

During the year ended December 31, 2017, net cash provided by financing activities was $10.4 million from the issuance of common stock related to a private placement financing.

Net cash used in financing activities was $11,000 for the three months ended March 31, 2017, and was primarily a result of payments on our financed equipment.

Net cash provided by financing activities was $1.4 million for the three months ended March 31, 2018, and was primarily a result of proceeds from the issuance of common stock related to a private placement financing.

OFF-BALANCE SHEET ARRANGEMENTS

We do not engage in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, as a part of our ongoing business. Accordingly, we did not have any off-balance sheet arrangements during any of the periods presented.

RELATED PARTY TRANSACTIONS

Information concerning related party transactions is set forth in the section captioned “Certain relationships and related party transactions.”

Contractual Obligations

Our principal obligations consist of the operating lease for our facilities. The following table sets out, as of December 31, 2017, our contractual obligations due by period (in thousands):

	Payments due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations[1]	$4,855	$ 517	$1,014	$961	$ 2,363
Equipment Financing	63	44	19	—	—
Total	$4,918	$ 561	$1,033	$961	$ 2,363

[1] Consists of obligations under multi-year, non-cancelable building leases for our facilities in Carlsbad, California. The leases expire between May 2018 and December 2027.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related

disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this prospectus, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue recognition

Product Sales

We recognize revenue from product sales when the following four criteria have been met: (i) the product has been shipped or services have been performed and we have no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of provisions for expected returns and cash discounts.

None of our sales contain right-of-return provisions and we have historically only experienced nominal returns. However, we estimate a provision for expected returns for the catheter sales used in our DABRA laser system. The provision is based on our best estimate of the number of products that will be returned as defective products based on the nature of the consumable. No provision is made for expected returns from other product sales, including the sales of devices, as we do not have a history of returns. If it becomes known that actual return rates deviate from our original estimates, the provision for expected returns will be adjusted accordingly. The provision for expected returns is recorded as a reduction of accounts receivable and product sales.

We also offer certain cash discounts associated with the sales of our products. These discounts are negotiated on a transaction by transaction basis and therefore do not include any estimate at the time of sale. The discounts are recorded as a reduction to accounts receivable and product sales.

For shipment of our products, we take into account the time at which to recognize revenue, generally this is when title and risk of loss is transferred.

Multiple Element Arrangements

We regularly enter into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include an instrument and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

Arrangement consideration is then allocated to those separate units of account based on their relative selling price. When applying the relative selling price method, the selling price for each deliverable is determined using the following hierarchy: (i) vendor-specific objective evidence, or VSOE, of the selling price; (ii) third-party evidence of selling price; or (iii) best estimated selling price. Our records revenue related to these multiple deliverables as products are delivered and services are performed. In order to establish VSOE of selling price, we must regularly sell the product or service on a standalone basis with a

substantial majority priced within a relatively narrow range. In cases where there are not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then we utilize best estimated selling price, or BESP.

We determine BESP for an individual element based on our average selling price of that discrete element during the annual period, excluding transactions that are not representative of standalone sales. We regularly review and maintain our BESP and update these estimates at least annually.

Billable Service Arrangements

Revenue from billable services, including repair activity, is recognized when the service is provided.

Extended Warranty Arrangements

Revenues received with respect to extended warranties on products are recognized over the duration of the extended warranty period on a straight-line basis.

Lease Arrangements

We also derive revenue pursuant to product lease agreements. These leases are classified as operating leases in accordance with the relevant accounting guidelines, and the related revenue is recognized on a straight-line basis.

Distributor Transactions

In certain markets, we sell products and provide services to customers through distributors that specialize in medical device products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. These transactions are accounted for in accordance with our revenue recognition policy described herein.

Stock-based compensation expense

We evaluate whether an award should be classified and accounted for as a liability award or equity award for all stock-based compensation awards granted.

Stock-based compensation for liability awards issued to employees and nonemployee service providers is measured based on fair value of the award using the Black Scholes option pricing model. Changes in the fair value of a liability incurred under a share-based payment arrangement that occur during the requisite service period are recognized as compensation cost over that period. The percentage of the fair value that is accrued as compensation cost at the end of each period is equal to the percentage of the requisite service that has been rendered at that date. Any difference between the amount for which a liability award is settled and its fair value at the settlement date is recorded as an adjustment to compensation cost in the period of settlement.

Stock-based compensation expense for equity instruments issued to employees and nonemployee service providers is measured based on estimating the fair value of each stock option on the date of grant using the Black Scholes option pricing model. Equity instruments issued to nonemployees are valued using the Black Scholes option pricing model and are subject to revaluation as the underlying equity instruments vest.

We recognize stock-based compensation expense as follows:

	Employees	Nonemployees
Service condition only	Straight-line	Re-value through the performance commitment date
Performance criterion is probable of being met:		
Service criterion is complete	Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence	Re-value the award once the performance criterion is considered probable of occurrence and recognize expense for the then fair value of the award
Service criterion is not complete	Straight-line	Straight-line, except the award is re-valued through the performance commitment date
Performance criterion is not probable of being met	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above

As of December 31, 2016 and 2017, and March 31, 2018, all stock-based compensation awards have been classified as liabilities in the financial statements which is revalued at each reporting period with the change in fair value recorded to compensation expense. The fair value of the stock-based compensation liability was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted below:

- *Fair value of our common stock*—Our shares are not traded in any public market. The common stock value as of the date of grant was based on the share price of recent equity issuances, if available. If there were no such recent transactions, our share valuation was estimated using both the income and market approaches, which were weighted 50% each. A discount of 35% was then applied for lack of marketability for our common stock. As of the reporting date for each period presented, the dates at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with new third party investors who were not previous shareholders of Ra Medical.
- *Risk-free interest rate*—The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term.
- *Volatility*—Expected volatility is based on the historical volatilities of certain “guideline” companies.
- *Expected dividend yield*—Expected dividend yield is based on dividends historically paid by us.
- *Expected life*—The expected life is based on the “simplified” method using the average of the term and vesting period.

For stock awards after the completion of this offering, our board of directors intends to determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. We have not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 have occurred.

If ownership changes within the meaning of IRC Section 382 have occurred, it could restrict our ability to use NOL carryforwards and research and development tax credits generated since inception. Limitations on our ability to use NOL carryforwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

Internal Control Over Financial Reporting

In connection with our 2017 audit, as part of the restatement to the 2016 financial statements described in Note 3 to the annual financial statements, we identified a material weakness in the design of our internal controls related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication and authorization of stock option awards which were not validly authorized. While we have designed and implemented, or expect to implement, measures that we believe address these control weaknesses, we continue to develop our internal controls, processes and reporting systems by, among other things:

- hiring qualified personnel with expertise to perform specific functions, including our Chief Financial Officer;
- the engagement of third party legal counsel to assist in the administration of capital stock transactions; and
- designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly,

there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

Jobs Act Accounting Election

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption. See Note 2 to the interim condensed financial statements included elsewhere in this prospectus for a description of relevant new accounting pronouncements.

Quantitative And Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business, including the effects of interest rate changes and foreign currency fluctuations. Information relating to quantitative and qualitative disclosures about these market risks is described below.

Interest Rate Sensitivity

We had cash and cash equivalents of $7.1 million as of March 31, 2018, which came from sale of our products and services and, to a lesser extent, private placements of common stock and debt financing arrangements. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Most of our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

BUSINESS

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of the DABRA laser system and disposable catheter, together referred to as DABRA, in the United States. Following the temporary placement period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements, or Usage Agreements, with each customer. The terms of the Usage Agreements vary by customer, but each Usage Agreement provides for the specific terms of continued use of DABRA, including the monthly maintenance fees. As of June 30, 2018, we had a U.S. installed base of 31 DABRA laser systems, eight of which have signed Usage Agreements with us, and the remainder of which are temporarily placed for use in demonstrations, trials, or training. DABRA is cleared by the U.S. Food and Drug Administration, or FDA, as a tool for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease, which includes peripheral artery disease, or PAD, which commonly occurs in the legs. We intend to pursue additional uses for DABRA, including seeking regulatory clearance for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other venous and arterial occlusions, or blockages in the veins or arteries. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA. DABRA (Destruction of Arteriosclerotic Blockages by Laser Radiation Ablation) is our minimally-invasive excimer laser and disposable catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging. Recent analysis suggests that 17.6 million people in the U.S. suffer from PAD. However, only 20-30% of PAD patients are actively being treated.

Current treatments for vascular blockages associated with PAD are largely endovascular and include angioplasty, stenting and atherectomy. Bypass surgery, which was frequently used in the past, was costly and often resulted in complications, including high levels of post-surgery pain and lengthy hospital stays and recovery times. Endovascular treatments employ catheter-based products for the displacement or removal of plaque. These treatments also have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease. We believe one of the main contributing factors to high restenosis, or the reaccumulation of blockages, rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Angioplasty balloons,

invented in the 1970's, held a great deal of promise, but the trauma due to their inflation often causes the vessel to reocclude either immediately or over time. Stents, invented in the 1980's, were developed to help keep the arteries open. However, stents can also promote reocclusion and are susceptible to fractures. Atherectomy devices, including the excimer laser, invented in the 1990's, were developed to overcome the drawbacks of angioplasty balloons and stents, which push the plaque to the side of the vessel. DABRA was designed to remove the plaque with less trauma in order to improve patient outcomes when compared to other competing devices.

DABRA is a novel technology for use in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease. We believe that our liquid-filled, full aperture ratio catheter allows for a less traumatic endovascular treatment for the removal of vascular blockages and offers significant benefits over competing treatments and therapies. DABRA is easy to use and can cross and debulk, or reduce or remove, a broad range of blockage types without the use of a guidewire. Although DABRA is suitable for use as a monotherapy, or a therapy that uses one type of treatment, it is predominantly used with angioplasty balloons and also can be used adjunct to drug-eluting balloons, stents, and other endovascular treatments. DABRA employs photochemical ablation, or the removal of body tissue by using photons, to remove blockages by breaking the bonds of the obstructing plaque directly. Unlike many treatments for PAD and other vascular diseases that may damage the arterial wall, DABRA quickly photochemically dissolves plaque with minimal vascular trauma. DABRA is minimally invasive and designed to not stretch the arterial walls or penetrate the layers of arterial tissue known as the subintimal space, which can lead to dissection, or a tear in the inner lining of the vessel wall, or perforation, or a hole or a break in the vessel wall, although these events may still occur with DABRA and other competing products. We believe that endovascular treatments using DABRA may be more durable and longer lasting than treatments using other devices because of the reduced mechanical trauma, thermal trauma, and barometric trauma, or trauma due to change in pressure inside the vessel. Independent in vivo and in vitro research studies have demonstrated that 308 nanometer excimer laser light, which is the same wavelength used in DABRA, increases T-cell apoptosis, or cell death, which may produce an immunosuppressive effect. While we have not established the benefits of this potential immunosuppressant effect in the vasculature, or blood vessels such as arteries or veins, we intend to conduct a registry or study to identify any immunotherapeutic benefits.

The safety and effectiveness of the DABRA laser system and disposable DABRA catheter is supported by our pivotal study, a non-randomized, single-arm, prospective, multi-site study conducted to evaluate plaque photoablation using DABRA in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease. The study enrolled 64 patients at four sites with both above-the-knee and below-the-knee lesions. The final study results demonstrated 94% effectiveness in successful crossing of the target lesion based on angiographic analysis, or a medical imaging technique used to visualize the inside of blood vessels, at time of the procedure with 0% reported serious adverse events. In a study conducted by Spectranetics Corporation, or Spectranetics, as part of its 510(k) application for its CLiRpath Excimer Laser Catheter device, which was the predicate device for our 510(k) application, Spectranetics reported a 79% crossing success with its catheter device and a 72% procedure success in a total of 47 cases. Cumulatively, Spectranetics reported that there were 16, or 34%, serious adverse events reported during the six month follow-up period with the most frequently observed event being reintervention, which occurred in six, or 13%, of cases. The endpoints of both studies were at the time of procedure and at 30 days. Although our pivotal study was not head-to-head with the Spectranetics study, and we may not claim superiority of safety or efficacy, we believe that the patient population in our pivotal study that supported our 510(k) application was substantially similar to the patient population in the Spectranetics study.

In May 2017, we received FDA 510(k) clearance to market the DABRA laser system and disposable DABRA catheter in the U.S. for intended use in ablating a channel in occlusive peripheral vascular disease. In June 2018, we completed our 12 month commercial launch period, which included training,

production, and staffing for the marketing of DABRA in the United States. We market DABRA in the U.S. through our direct sales force, comprised of 15 sales representatives as of June 30, 2018, which places lasers in catheterization laboratories that perform high volumes of endovascular procedures, including atherectomy on peripheral arteries. We have plans to increase sales by further expanding this organization. We are initially focused on placing DABRA in outpatient based laboratories, or OBLs, and subsequently we intend to expand into the hospital catheterization laboratory market. Reimbursement claims for DABRA procedures are typically submitted by the provider to Medicare or another third-party payor using established Current Procedural Terminology, or CPT, codes for atherectomy procedures. DABRA was granted CE mark clearance in September 2016, and we sell systems through distributors in select non-U.S. countries.

Pharos. Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. We have also received clearance to market Pharos from the European Medicines Agency, or EMA, China Food and Drug Administration, or CFDA, and South Korea Ministry of Drug Safety, or KFDA, in the applicable jurisdictions. Pharos offers significant benefits to patients. The targeted nature of our treatment allows the operator to spare healthy tissue from exposure to the ultraviolet light making the treatment faster and safer than some other forms of phototherapy, or light therapy. The light induces T-cell apoptosis which we believe may produce an immunosuppressant effect. For instance, Pharos is not contraindicated for children and pregnant women, allowing for their treatment. In addition, we believe excimer laser treatments can put patients into remission from certain diseases. Treatment with Pharos differs from topical treatments, such as steroids and vitamin D derivatives, which may require frequent ongoing application. Treatment with Pharos also differs from pharmaceuticals treatments, which may be associated with systemic side effects.

Psoriasis is a chronic autoimmune disorder that causes cells to build up rapidly and affects the surface of the skin. The National Psoriasis Foundation reports that psoriasis affects approximately 7.5 million people in the U.S., which accounts for over 2% of the domestic population. Vitiligo is an autoimmune condition in which the skin turns white due to the loss of melanocytes, cells that produce the pigment melanin, which gives skin color. Vitiligo affects 1-2% of the population globally. Atopic dermatitis, more commonly known as eczema, is a chronic eczematous skin disease. There are approximately 17.8 million people in the U.S. suffering from atopic dermatitis. Leukoderma is the localized loss of pigment in the skin due to several causes including vitiligo.

Vascular Disease

Vascular disease refers to diseases of the heart and blood vessels located throughout the body. The most common cause of vascular disease is atherosclerosis. Atherosclerosis is a progressive, degenerative condition in which plaque, consisting of lipids, cholesterol, calcium and other substances found in the blood stream, accumulates on the arterial wall. Plaque occurs in several different forms and may be located throughout the arterial system. Plaque varies in composition, with portions that are hard and brittle, referred to as calcified plaque, and other portions that are fatty or fibrous. Endovascular treatments for atherosclerosis are performed in a catheterization laboratory located in an OBL or hospital. These patients are diagnosed by their primary care physician, podiatrist, or other specialist, and then treatment is performed an interventional cardiologist, interventional radiologist, or vascular surgeon.

PAD is atherosclerosis of the extremities, most commonly in the legs. Smoking, genetic predisposition, diabetes, aging, and obesity may significantly increase the risk of developing PAD. Plaque build-up reduces blood-flow to the surrounding tissue, causing claudication, pain or cramping in the leg, the most

common early symptom of PAD. Symptoms may progress to include numbness, tingling or weakness in the leg and, in severe cases, burning or aching pain in the foot or toes.

As PAD progresses, additional symptoms may develop on the legs, including cooling, color changes, or sores that do not heal. If untreated, PAD can lead to critical limb ischemia, or CLI, a condition where there is not enough oxygenated blood being delivered to the limb to keep the tissue alive. As of June 2017, the SAGE Group reported that conservatively 22 to 30 million people suffer from CLI worldwide. If untreated, CLI may result in ulceration, infection, or gangrene in the feet and legs and eventually limb amputation or death.

Market Overview

Recent analysis suggests that 17.6 million people in the U.S. suffer from PAD. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic and many dismiss symptoms as normal signs of aging. Research indicates only 20-30% of PAD patients are actively being treated.

Without treatment, the disease can result in severe complications and lead to amputation. The most common reason for amputation today is PAD, and up to 180,000 amputations are performed annually in the U.S. Despite the relative undertreatment of PAD, the atherectomy devices industry achieved a $1.08 billion market in 2017 and is estimated to grow at CAGR of over 6% from 2018 to 2022. Higher diagnosis and intervention rates resulting from greater physician and patient awareness of PAD, as well as higher prevalence, are helping drive the market opportunity for PAD treatments.

We believe that the following factors are contributing to a growing diagnosed patient population:

- ***Increased Awareness.*** Recent emphasis on PAD education from medical associations, insurance companies and online medical communities, as well as publication in medical journals is increasing public and physician awareness of PAD risk factors, symptoms and treatment options.
- ***Evolving Physician Practice Patterns.*** Given that many patients with CAD also have PAD, we believe that interventional cardiologists and vascular surgeons are increasingly screening patients for both diseases. As a consequence, we believe that physicians are diagnosing more cases of PAD. In addition, we believe that heightened awareness of PAD, its symptoms and treatment options is leading to increased referrals.

Conventional Means of Treatment and Their Limitations

Physicians typically treat patients with mild to moderate PAD through non-invasive management, including exercise and prescription medication, and, if symptoms worsen, may recommend interventional or surgical procedures. Some patients who initially are diagnosed with severe PAD are treated immediately through interventional or surgical procedures.

Non-Invasive Management. For many diagnosed cases of PAD in the U.S., lifestyle changes, including improved diet, regular exercise and smoking cessation, as well as drug treatment are often prescribed. Although these measures can be effective, many people are unable to sustain them. In addition, these measures may reduce the symptoms, but do not treat the underlying causes of the disease. Physicians may also prescribe medications that lower cholesterol and reduce blood pressure. These drug therapies are generally prescribed for the life of the patient and do not treat the obstruction, making them an ineffective treatment for many patients. As a result, many of these patients will ultimately require more aggressive treatments.

Interventional Procedures. When PAD progresses beyond claudication, physicians may advise intervention, often beginning with minimally-invasive procedures. Minimally invasive endovascular treatments include balloon angioplasty, stents, and atherectomy devices. These treatments have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease. We believe that there are over 500,000 annual endovascular procedures for the treatment of PAD in the U.S. Angioplasty and stenting are the most commonly performed minimally-invasive interventional treatments.

- ***Angioplasty.*** In an angioplasty procedure, a long, thin tube, or catheter, with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guide wire that directs the catheter to the affected area. The balloon is then inflated, compressing the plaque and stretching the arterial wall. While angioplasty catheters are relatively easy to use, they stretch the arterial wall, often leading to dissections of, and damage to, the arterial walls. Angioplasty does not remove the plaque, which remains in the artery. In addition, angioplasty is not well suited to treat highly calcified lesions, lesions concentrated on one side of the arterial wall, or lesions that occur at bifurcations, all common manifestations of PAD in the leg. Further, most angioplasty procedures for PAD are performed with the additional use of a stent.
- ***Stenting.*** Stenting is performed in tandem with angioplasty. A stent is a wire-mesh tube that acts as a scaffold inside the artery to keep it open. Stents are currently available in a wide range of varieties. Despite their widespread use, stents may cause injury and inflammation to the arterial wall during placement and continued trauma post-procedure. Stents placed in the legs are subject to forces and compression that may fracture or crush them, leading to reduced blood-flow and further vessel trauma. Once a stent is implanted, it cannot be removed, which may limit future treatment options such as angioplasty, additional stenting, atherectomy and bypass.
- ***Atherectomy.*** Atherectomy is a procedure to remove plaque. There are several types of atherectomy devices, including directional, rotational and laser, each with different mechanisms of action to remove plaque. Atherectomy treatments are frequently used with a stent or balloon. Atherectomy technologies can damage the vessel walls, which may increase the risk of restenosis. For example, cutting devices, such as directional or rotational devices, introduce significant mechanical trauma and other commercial laser devices have a significant thermal component due to the arrangement of the delivery catheter, both causing trauma to the artery.

Surgical Procedures. Most PAD patients are treated endovascularly. Many of these patients, including diabetics, are not candidates for surgical procedures. However, surgery is used when non-invasive management or interventional procedures have failed or if the patient is diagnosed when PAD has progressed to an advanced state.

- ***Bypass Surgery.*** More severe cases of PAD may be treated by surgeons with bypass surgery. The blood-flow is diverted around the occluded area using a synthetic graft or harvested vessel. Bypass surgery is performed by physicians in an operating room with the patient under general anesthesia and requires multi-day hospital stays for healing and rehabilitation. General anesthesia and the potential for surgical infections make this approach less suitable for patients with conditions such as high blood pressure, heart failure, chronic obstructive pulmonary disease or poor kidney function.
- ***Amputation.*** CLI is a serious form of PAD caused by severe lack of blood-flow to the legs. Physicians may recommend full or partial amputation of the leg or foot for patients with CLI. Up to 180,000 amputations occur annually in the U.S. as a result of PAD.

Our Solution

Strengths of Our Approach

DABRA includes a portable excimer laser system combined with proprietary, single-use catheters that, together, represent a competitive atherectomy solution for the minimally invasive endovascular treatment of blockages in the vasculature. DABRA represents a novel approach to the treatment of a broad range of vascular blockages that is safe and effective, easy to use, and competitively priced. We believe that the principal benefits of DABRA are:

- ***Safety***. DABRA is designed to track the patient's true lumen, or the center of the artery, and not to penetrate between the layers of arterial structure known as the subintimal space. Damage or stretching of the arterial walls, which can lead to dissection or perforation, may be reduced. No serious adverse events were reported in our 2017 pivotal study, which followed 38 subjects for 180 days, or reported in our post-market surveillance for DABRA. In our post-market surveillance, the most frequent complication reported to us has been clinically non-significant vessel perforation.
- ***Efficacy***. Unlike many treatments for PAD that do not remove plaque, DABRA employs photochemical ablation to disintegrate plaque by breaking its chemical bonds, thereby reducing the plaque to the components of its fundamental chemistry without generating potentially harmful particulates. We believe that eliminating plaque while minimizing injury to the arterial wall may minimize the rate of restenosis. We followed 38 subjects from our pivotal study to 180 days thereafter and all of the subjects were determined to be completely free of target lesion revascularization, or the need to retreat the lesion.
- ***Utility***. DABRA enables physicians to remove plaque from long and calcified lesions in arteries located in the lower extremities both above- and below-the-knee. DABRA is able to cross and debulk a wide variety of plaque, removing vascular blockages that other products are unable to cross without the use of a guidewire. For example, in patients with a chronic total occlusion, or CTO, the physician may use DABRA to cross the CTO prior to alternative treatments consisting of balloon angioplasty and possibly stenting.
- ***Ease of Use***. DABRA employs techniques similar to those used in angioplasty, which are familiar to the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the U.S. who are generally trained in endovascular techniques. This significantly increases the number of physicians who are able to perform the procedure compared to surgical alternatives that must be performed by highly-trained vascular surgeons.
- ***Cost and Time Efficient***. We believe that because our single-use DABRA catheters are priced competitively and because we provide the DABRA laser system for a nominal monthly fee, without requiring the purchase of capital equipment, DABRA is a cost-effective solution for providers. Providers are also eligible for reimbursement for procedures performed using DABRA using existing Current Procedural Terminology, or CPT, codes. In addition, DABRA's easy setup and fast ablation speed reduce both treatment and fluoroscopy time, or x-ray exposure time, for the patient, physician, and staff, improving the providers' patient throughput. The average lasing time in our pivotal study was approximately two and a half minutes per procedure.
- ***Immunotherapeutic Benefits***. Research performed using 308 nanometer laser energy, the wavelength of Pharos, demonstrated increased T-cell apoptosis, which may produce an immunosuppressant effect. Unlike with Pharos, where we can measure the degree and speed of clearance of disease and quantify the remission time, with DABRA we have not established the benefits of this immunosuppressant effect in the vasculature. We intend to conduct a registry or study to identify any immunotherapeutic benefits.

Our Strategy

Our goal is to become the leading medical device company marketing excimer lasers as tools for the treatment of endovascular diseases. Key elements of our strategy to achieve this goal are:

- ***Driving physician awareness of DABRA***. Our program to educate physicians regarding DABRA's value proposition consists of presentations and exhibits at industry conferences, advertising in medical journals, direct visits, webinars, and calls.
- ***Creating patient awareness of DABRA***. We are establishing marketing and support programs with physicians and patient advocacy organizations to create patient awareness of PAD treatment options in order to generate demand for our products.
- ***Expanding DABRA sales***. We provide physicians with clinical training to drive adoption and utilization of DABRA. We believe that a strong sales team to train physicians on the use and the benefits of DABRA will increase sales. We expect to continue to expand the clinical sales team through 2018 and beyond.
- ***Extending DABRA to additional indications***. We plan to leverage our product technology and research and development expertise to develop DABRA for additional vascular indications, such as CAD and in-stent restenosis.
- ***Expanding commercial opportunities for DABRA internationally***. We received the right to affix the CE mark to DABRA in the third quarter of 2016, permitting DABRA to be marketed and sold in Europe and other CE mark markets. We plan to expand commercial opportunities for DABRA internationally through obtaining additional regulatory approvals and expanding our relationships with international distributors.
- ***Optimizing existing manufacturing capabilities to generate operating leverage***. We design, develop and manufacture DABRA in-house using components and sub-assemblies provided by third-party suppliers. We believe that by controlling the manufacturing and assembly of our products we are able to innovate more quickly, produce higher quality products, and increase our manufacturing scale in a cost-effective manner. We intend to use our design, engineering, and manufacturing capabilities to further improve the efficiency of our manufacturing process and expand our margins.
- ***Expanding our product offerings***. We believe that we will be able to leverage our technology and sales platform to expand our endovascular offerings with ancillary endovascular devices such as angioplasty balloons, guide catheters, and introducers. We intend to achieve this through our internal development efforts and with selective licenses, alliances or acquisitions of complementary products, technologies or businesses.

The DABRA Product

DABRA combines a portable excimer laser console with proprietary, single-use catheters for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease in both above- and below-the-knee lesions. DABRA benefits from our expertise in excimer lasers gained from over a decade developing, manufacturing, testing, marketing, and servicing the Pharos excimer laser for dermatological diseases.

We believe that DABRA is the only endovascular device that crosses chronic total occlusions and removes plaque without a guidewire. The most important aspect of DABRA for the vascular market is the catheter, which conducts energy from the laser to the vascular blockage. The laser energy travels through the catheter and ablates the blockage, reducing it to chemicals that are found naturally in the bloodstream. The catheters are sterilized single-use only and specifically designed for our laser-based systems. The DABRA catheter uses a liquid-filled plastic tubing instead of glass fiber optic construction allowing for the efficient and precise delivery of the laser energy.

The DABRA Laser

The DABRA catheter is a single-use, 5 French gauge catheter that does not use a guidewire to navigate vasculature and which typically stays within the normal area in which blood is flowing or true lumen, even while crossing blockages. It is a full aperture ratio forward cutter, delivering fast ablation of all types of plaque, without the “dead-space” of fiber optic bundle catheters. It produces a high quality lumen while minimizing trauma to the vasculature. The DABRA catheter has a 1.5 millimeter blunt-tip design and a working length of 150 cm that tracks the true lumen, navigating the vascular curves. DABRA catheters have been used with a variety of introducers and 7 French gauge guide catheters. They have been used in both above- and below-the-knee procedures, including axially, femorally, both antigrade and retrograde, from popliteal access and pedal access, both anterior tibial and posterior tibial. DABRA removes plaque by photochemical ablation, limiting the vascular trauma caused by mechanical forces, acoustic or thermal energy, or vapor bubbles, used in competing products.

The DABRA Catheter

The DABRA excimer laser is the power source for DABRA catheters that generates a laser light by a software controlled 308 nm excimer laser source that produces 308 nanometer ultraviolet-B photons that are directed to the catheter through a lens to photochemically ablate vascular blockages, reducing calcium, thrombus, and atheroma into their fundamental chemistry, minimizing downstream debris.

DABRA ablation produces fast treatment times and minimizes fluoroscopy time. The laser is small enough for most catheterization laboratories, weighs approximately 110 pounds, and is easily portable around and between rooms. It is easy-to-use, features a simple and intuitive operator-interface, plugs into a standard 110-volt outlet, and does not require any pumps or fluids.

The DABRA Procedure

During the procedure, the physician inserts the proximal end of the disposable DABRA catheter into the laser console. Using the buttons next to the screen of the console, the physician enters the calibration mode and inserts the catheter into the calibration port of the console to perform the calibration. The physician sets the treatment settings on the touch screen. The physician then inserts the catheter into the support catheter and under

fluoroscope, advances the catheter to the target lesion. The physician uses the footswitch to activate the laser unit and slowly advances the catheter to ablate the target lesion.

Depending upon the type of lesion, DABRA can cross blockages at a rate of up to one centimeter per second. The DABRA procedure is typically performed under local anesthesia in a catheterization laboratory. Procedures performed using DABRA have an approximate two and a half minute total lasing time. A patient treated in an OBL is discharged the same day.

Clinical Studies and Patient Data

Pre-Marketing Studies. We applied and received FDA IDE approval to treat up to 50 adult patients in the U.S. for our pivotal study. It was a non-randomized, single-arm, prospective, and multi-site study that enrolled 64 patients at four sites. The objective of the study was to evaluate plaque photoablation using DABRA in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease in patients with Rutherford categories 3, 4, 5 and 6. The primary efficacy endpoint was the successful crossing of the target lesion based on angiographic analysis at time of the procedure. The safety endpoint was device-related major adverse events at the time of the procedure. It was conducted at four centers including the California Heart and Vascular Center, an OBL in El Centro, California, Centro Medico Excel, a hospital in Tijuana, Mexico, the University of California, San Diego, a major teaching hospital in San Diego, California, and Wesley Medical Center, a hospital in Hattiesburg, Mississippi. As part of the inclusion criteria for the DABRA study, the target blockage must have been refractory to guidewire crossing. The average lasing time in our study was approximately two and a half minutes and the average lesion measured over seven centimeters, which is representative of a typical patient suffering from severe lower extremity vascular disease. The analyses pre- and post-treatment were performed using standard angiographic and ultrasonic tools which are commonly used in commercial catheterization laboratories.

The study was closed to enrollment on May 24, 2017 when we received 510(k) clearance for DABRA and contained data on 64 patients. The final study results demonstrated 94% effectiveness with 0% reported serious adverse events. Furthermore, in our study, 64 lesions crossed were above the knee, or approximately 85%, and 11 lesions crossed were below-the-knee, or approximately 15%. In a study conducted by Spectranetics as part of its 510(k) application for its CLiRpath Excimer Laser Catheter device, which was the predicate device for our 510(k) application, Spectranetics reported a 79% crossing success with its catheter device and a 72% procedure success in a total of 47 cases. Cumulatively, Spectranetics reported that there were 16, or 34%, serious adverse events reported during the six month

follow-up period with the most frequently observed event being reintervention, which occurred in six, or 13%, of cases.

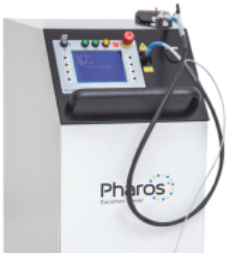
The endpoints of both studies were at the time of procedure and at 30 days. Although our pivotal study was not head-to-head with the Spectranetics study, and we may not claim superiority of safety or efficacy, we believe that the patient population in our pivotal study that supported our 510(k) application was substantially similar to the patient population in the Spectranetics study. The following is a summary of our clinical study for DABRA:

	Patients (64)		Age					
			M		F			
	M	F	Mean	Median	Mean	Median	Patient Successes	# of Serious Adverse Events
Totals:	48	16	71	69	73	77	60	0

Lesion Locations	Number of Lesions
CFA	2
Iliac	1
Proximal SFA	12
Mid SFA	30
Popliteal	14
Peroneal	2
TP Trunk	2
Anterior Tibial	8
Posterior Tibial	1

We followed 38 subjects from our pivotal study to 180 days thereafter and all of the subjects were determined to be completely free of target lesion revascularization, or the need to retreat the lesion.

The Pharos Product



The Pharos Laser

Pharos is a powerful, monochromatic, or single-wavelength, xenon-chlorine, 308 nanometer ultraviolet-B excimer laser used by physicians as a tool to treat chronic skin diseases, including psoriasis, vitiligo, atopic dermatitis, and leukoderma. We launched Pharos in 2004. Pharos does not use heat and does not ablate lesions, and treatments are generally painless. Pharos' proprietary hand piece features an integrated adjustable spot size and aiming beam that accurately targets only the diseased tissue while sparing the healthy skin from exposure. The laser beam is easily contoured to accommodate the shape of the lesion for fast and precisely targeted treatments with constant fluence, or stream of photons crossing a unit area. No templates or attachments are required. Its flat-top, no hot-spot beam profile delivers uniform dosing for optimal results. Pharos is small enough for most treatment rooms, intuitive to use, and uses a standard 110-volt outlet.

The Pharos treatment is generally performed in a dermatology treatment room in an office, clinic or hospital. In most states and countries in which we have received regulatory approval, the treatment can be applied by a nurse or technician. The laser is calibrated, the desired dose is entered, and the hand piece is directed to the patient. The treatment is delivered through a hand piece that has a distance gauge which is placed on the patients' skin and is operated by a foot switch. The hand piece is moved to the appropriate lesion location and the process is repeated until all of the lesions have been dosed.

We believe that the principal benefits of Pharos are:

- ***Wavelength.*** Studies have shown that the action spectrum, or the rate of a physiological activity plotted against wavelength of light, for immunologically modulated skin disorders is centered at about 308 nanometers. Pharos is a 308 nanometer laser, making it ideally suited for use as a tool in the treatment of these disorders.
- ***Energy.*** The energy from excimer lasers has been shown, in both in vivo and in vitro studies, to have almost four times the T-cell apoptosis generation than non-laser sources. Pharos is a pulsed laser capable of producing very high peak powers and we believe that this may produce an immunosuppressive effect.
- ***Collimation.*** Ultraviolet-B light has a very shallow penetration into the skin, typically less than 100 microns. Although the skin tends to scatter the light, collimation, or keeping the light rays parallel, helps prevent reflection and improves the dose delivery. Pharos has a moderately collimated beam and this collimation allows for treatment in intertriginous areas, such as the groin and armpits, and mucosal areas, such as the mouth and ears, without compromising dose.
- ***Targeting.*** Applying the laser energy only to the diseased tissue not only spares the healthy tissue from exposure, but also allows the operator to increase the dose to the affected areas. We believe that Pharos is the only system that has an integrated adjustable spot size offering continuous beam adjustment from a large square to a small circle.
- ***Footprint.*** Dermatological treatment rooms are small and often crowded with other equipment. Pharos has a small footprint and is among the lightest excimer lasers currently marketed, allowing physicians to conserve space and easily move the system.

There are essentially three main types of current treatments for dermatological skin disorders, which each have limitations, as listed below:

- ***Topical therapies.*** These can include corticosteroids, vitamin D3 derivatives, coal tar, anthralin and retinoids, among others, that are sold as a cream, gel, liquid, spray, or ointment. The efficacy of topical agents varies from person to person, and these products are commonly associated with poor compliance or side effects that include irritation, redness, and thinning of the skin.
- ***Phototherapy.*** There are several ultraviolet lamp systems that deliver ultraviolet-A and ultraviolet-B light for the treatment of skin conditions. Broadband ultraviolet therapy can be less desirable than targeted laser machines due to exposure of non-diseased skin and limited ability to deliver high intensity light, requiring more treatment sessions and increasing cancer risk.
- ***Systemic medications including biologicals.*** There are a number of prescription medications available, which are delivered orally or by injection. Generally, these drugs are administered only after both topical treatments and phototherapy have failed, or for people who have severe disease. Some of the side effects include risks of infection or death.

Dermatological Disease

Dermatological disease refers to diseases of the skin caused by imbalance in the physiological condition of the skin. There are over 3,000 different skin conditions and diseases, including psoriasis, vitiligo, and atopic dermatitis. Psoriasis is a chronic autoimmune disorder that causes cells to rapidly accumulate and affects the surface of the skin. The extra skin cells form scales and red patches, or flares, which are itchy and sometimes painful. There is no known cure and multiple rounds of treatments are required to bring the disease under control. Vitiligo is an autoimmune condition causing the skin to turn white due to the

loss of pigment from the melanocytes, cells that produce the pigment melanin, which gives skin color. There is no known cure. However, some medical treatments can reduce the severity of the condition. Atopic dermatitis, a chronic eczematous skin disease, can result in itchy, red, swollen, and cracked skin.

Additional proliferative skin disorders include alopecia areata, dyshidrotic eczema, and cutaneous T-cell lymphoma, or CTCL. Alopecia areata is a condition in which hair is lost from some or all areas of the body. Dyshidrotic eczema is a skin disease characterized by itchy blisters on the palms of the hands and bottoms of the feet. CTCL is a type of cancer of the immune system caused by a mutation of T-cells.

Market Overview

Psoriasis, atopic dermatitis and vitiligo are common skin disorders throughout the world. The National Psoriasis Foundation reports that psoriasis affects approximately 7.5 million people in the U.S., which accounts for over 2% of the domestic population. Globally, this skin condition is estimated to afflict over 125 million people. Direct and indirect healthcare costs related to psoriasis in the U.S. alone are roughly $11.25 billion annually. Lost time from work accounts for an additional $11.2 billion per year, as the majority of psoriasis patients miss an average of 26 days of work a year due to their disease. Currently, 17.8 million people suffer from atopic dermatitis in the U.S., making it one of the most common inflammatory skin diseases. Vitiligo is a pigmentation disorder that affects 1% to 2% of the population globally. Alopecia areata affects about 2% of the population in the U.S., or about six million people. There are approximately 30,000 CTCL sufferers in North America.

Sales and Marketing

We market and sell DABRA and Pharos primarily through our direct sales force in the U.S. As of June 30, 2018, we had a 15-person direct sales force in the U.S. with 12 persons focused on vascular and three persons focused on dermatology. Our sales force is organized by geographic sales territories, and each territory is managed by a sales manager who acts as the primary customer contact. We plan to continue to increase the size of our sales organization to expand our installed unit base and to increase utilization of the DABRA and Pharos. Our initial focus for DABRA is high-volume OBLs. We partner with distributors for DABRA and Pharos in select geographies outside of the U.S.

Our marketing department currently consists of five professionals. Our marketing program focuses on:

- educating physicians regarding the proper use and application of DABRA and Pharos;
- supporting physicians' efforts to enhance referral opportunities;
- improving patient and caregiver awareness of our treatments; and
- facilitating national and international marketing programs.

We use a targeted marketing approach to introduce our products to the medical marketplace. We primarily target our marketing efforts to practitioners through marketing materials, medical conferences and journals. In addition, we host seminars and webinars where industry leaders discuss case studies and treatment techniques using DABRA and Pharos.

Manufacturing

We manufacture our excimer lasers and catheters in our approximately 32,000 square foot facility located in Carlsbad, California. Our vertically integrated facility is ISO 9001 and ISO 13485 certified and is licensed by the state of California to manufacture our sterile single-use catheters in our controlled environments. We specify and source our supplies primarily from U.S.-based manufacturers, contracting with local suppliers to manufacture custom components. We carefully choose our suppliers to ensure that all components meet our quality standards, adhere to all applicable regulations, and meet our supply needs. We inspect, test, and

assemble our products under strict manufacturing processes supported by internal policies and procedures. We perform our own final quality control testing of all products before shipment. In addition to primary suppliers, secondary suppliers have been identified for contingency planning purposes for many key components. We audit our suppliers as required by our quality system and the FDA. We believe that our current manufacturing capacity is sufficient to produce enough lasers and catheters to meet our current expected demand for at least the next 12 months.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our competitors also include pharmaceutical companies that manufacture drugs for the treatment of PAD or other dermatological diseases. Our overall competitive position is dependent upon a number of factors, including product performance and reliability, manufacturing cost, and customer support.

Vascular blockages are currently treated with angioplasty balloons, stents, and atherectomy devices that include excimer laser ablation. Our major competitors for our vascular solutions include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., including Volcano Corporation and Spectranetics Corporation, Becton Dickinson and Company, including products from the C.R. Bard acquisition, and Abbott Laboratories. We believe that DABRA competes favorably with our competitors' products in terms of safety, ease of use, utility and cost.

Dermatological diseases are currently treated with phototherapy, topical therapies, and systemic medications. Our major competitors for our dermatological solutions include The Daavlin Company, National Biological Corp., STRATA Skin Sciences and large pharmaceutical companies producing biologicals. We believe Pharos competes favorably with our competitors' products.

Reimbursement

Our customers do not receive reimbursement for the purchase of our products. However, procedures performed using DABRA and Pharos are reimbursable using existing CPT codes. At this time the Company believes that the existing CPT codes are generally adequate to cover procedures performed using the Company's products, without the need to apply for separate product specific CPT codes. Sales of DABRA and Pharos in the U.S. depend in part on the availability of coverage and adequate reimbursement to our customers for use of our products from third-party payors, such as private health insurers, managed care organizations and government health programs, like Medicare, Medicaid, TRICARE and the Veterans Administration. Medicare's coverage and reimbursement policies are significant to our operations, as a large percentage of DABRA and Pharos procedure patients are Medicare beneficiaries, and private third-party payors often rely upon Medicare coverage and reimbursement policies in setting their own payment policies. However, no uniform coverage and reimbursement policy for services and products exists among third-party payors in the U.S. You should refer to the "Risk factors" section of this prospectus for risks related to reimbursement.

Procedures performed using DABRA and Pharos are generally reimbursed using the below CPT codes. The 2018 facility and non-facility reimbursement amounts are included in the table below. The non-facility reimbursement amounts are the payment rates for services performed in the OBL setting. Generally, the reimbursement is higher in the non-facility setting because the physician incurs the practice expense for providing the service.

2018 Medicare National Payment Amounts

DABRA LASER (Endovascular)

CPT Code	Non-Facility Reimbursement Amount	Facility Reimbursement Amount	Procedure
37225	$11,130.36	$636.83	Fem/popl revasc w/ather
37227	$15,061.51	$765.35	Fem/popl revasc stnt & ather
37229	$10,975.92	$742.31	Tib/per revasc w/ather
37231	$13,605.33	$798.11	Tib/per revasc stent & ather
37233	$1,464.46	$345.60	Tib/per revasc w/ather add-on
37235	$4,194.31	$420.48	Tib/per revasc stnt & ather

PHAROS LASER (Dermatology)

CPT Code	Non-Facility Reimbursement Amount	Facility Reimbursement Amount	Procedure
96920	$168.12	$68.76	Laser tx skin < 250 sq cm
96921	$184.32	$77.40	Laser tx skin 250-500 sq cm
96922	$250.92	$124.56	Laser tx skin > 500 sq cm

Market acceptance of the DABRA and Pharos devices is dependent on adequate payment levels from third-party payors to our customers. We receive payment from the provider, facility or other entity that purchases, leases, rents or uses the DABRA or Pharos devices and purchases related supplies. A physician who performs a procedure utilizing either device may be reimbursed separately by third-party payors for their services. Under Medicare, the physician would be reimbursed according to the physician's fee schedule in effect at the time of the procedure.

Reimbursement to facilities and physicians can vary substantially depending on the third-party payors' coverage and reimbursement policies and other factors. For example, the type and geographical location of the facility in which the procedure was performed may impact the level of reimbursement. In addition, the specific use of the product may impact reimbursement. For example, the Pharos treatment of psoriasis is reimbursable by Medicare and nearly all major insurance companies under three CPT codes that differ based on the affected area to be treated. As a result, there is wide variability in reimbursement, and third-party payor's reimbursement policies are subject to change. Further, requests for reimbursement are subject to challenge, reduction or denial by third-party payors.

Research and Development

The major focus of our research and development team is to leverage our existing technology platform for new applications. Future research and development efforts will involve continued enhancements to and cost reductions for DABRA and Pharos. We will also explore the development of other products that can be derived from our core technology platform and intellectual property. Our research and development team works together with our sales force to set development priorities based on communicated customer needs. The feedback received from our customers is reviewed and evaluated for incorporation into new products. Over the last two fiscal years, we have invested over $6.2 million in principal research and development programs ($1.7 million and $4.5 million for the years ended December 31, 2016 and 2017, respectively).

Patents and Proprietary Technology

Patents.

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patent, copyright, trademark and trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights. The protection of intellectual property has been and remains a priority for us. As of July 11, 2018, we own three issued patents and continue to pursue patent protection in five different patent families. In the patent family titled "Small Flexible Liquid Core Catheter for Laser Ablation in Body Lumens and Methods for Use," we own one issued U.S. patent, one issued Chinese patent and a pending European patent application which has received a Communication from the European Patent Office under Rule 71(3) indicating an intent to grant the application. A U.S. divisional application has also been filed in this patent family and remains pending. In the patent family titled "Methods and Devices for Treatment of Stenosis of Arteriovenous Fistula Shunts," we own one issued U.S. patent and three divisional applications remain pending in the U.S. A U.S. patent application titled "Laser Ablation Catheters Having Expanded Distal Tip Windows for Efficient Tissue Ablation" is currently pending in addition to a U.S. patent application titled "Catheter Grip Device and Method." A pending U.S. patent application titled "Liquid Filled Ablation Catheter with Overjacket" has been converted to a pending Japanese national stage application with plans to further convert this application into the national stage in the U.S., China and Europe. Our issued U.S. patents expire between 2035 and 2036, subject to payment of required maintenance fees, annuities, and other charges.

Trademarks

We own or have rights to trademarks that we use in connection with the operation of our business. We own or have rights to trademarks for Ra Medical Systems and our logo as well as other marks such as DABRA and Pharos.

Trade Secrets

We also rely upon trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

Government Regulation and Product Approval

United States

In the U.S., medical devices are subject to extensive regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act, or the FDC Act, and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending pre-market approval applications, or PMAs, issuance of warning letters or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class II devices provide intermediate levels of risk. They are subject to general controls, and some Class II devices

must also comply with special controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by FDA before they are marketed.

Generally, establishments that manufacture devices are required to register their establishments with the FDA and provide FDA a list of the devices that they handle at their facilities.

Pre-market Authorization and Notification

While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a pre-market approval, or PMA, application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices; or (iii) authorized the device to be marketed through the de novo process, generally applicable for novel Class I or II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because FDA has not yet called for PMAs for these devices.

510(k) Notification

Product marketing in the U.S. for most Class II and limited Class I devices typically follows a 510(k) pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. A predicate device may be a previously 510-(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications, or a product previously granted de novo authorization. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

There are three types of 510(k)s: traditional; special, for devices that are modified and the modification needs a new 510(k) but the modification does not affect the intended use or alter the fundamental scientific technology of the device; and abbreviated, for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review. The FDA intends to process special 510(k)s within 30 days of receipt, and abbreviated 510(k)s within 90 days of receipt. Though the FDA has a user fee goal to clear a traditional 510(k) within 90 days of receipt, the clearance pathway for traditional 510(k)s can take substantially longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FD&C Act, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDC Act. This provision allows FDA to classify a low- to moderate-risk device not previously classified into Class I or II.

PMA Approval

A product not eligible for 510(k) clearance must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction.

Results from adequate and well-controlled clinical trials are required to establish the safety and effectiveness of a Class III PMA device for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all preclinical, clinical, and other testing, and information relating to the product's marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA.

The PMA approval process is generally more expensive, rigorous, lengthy, and uncertain than the 510(k) premarket notification process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The FDA's review of a PMA application typically takes one to three years, but may last longer. If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a premarket notification. For significant risk devices, the FDA regulations require that human clinical investigations conducted in the U.S. be approved via an investigational device exemption, or IDE, which must become effective before clinical testing may commence. A nonsignificant risk device does not require FDA approval of an IDE. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. If the FDA disapproves the IDE within this 30-day period, the clinical trial proposed in the IDE may not begin.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to granting PMA approval, the FDA typically inspects the records relating to the

conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Clinical trials are typically conducted at geographically diverse clinical trial sites, and are designed to permit FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device. Clinical trials, for significant and nonsignificant risk devices, must be approved by an institutional review board, or IRB – an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Investigational devices may only be distributed for use in an investigation, and must bear a label with the statement: "CAUTION—Investigational device. Limited by Federal law to investigational use."

Postmarket Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act). In addition, we are subject to medical device reporting regulations that require us to report to the FDA, EMA, or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints that we have received rose to a level required to be reported to the FDA. We are currently evaluating and responding to the FDA's inspectional observations. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet.

The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products, and if we promote our products beyond their approved indications, we may be subject to enforcement actions or prosecution arising from that off-label promotion. Violations of the FDCA relating to the inappropriate promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

For a PMA or Class II 510(k) or de novo device, the FDA also may require post-marketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, quality-control, manufacture, packaging, and labeling procedures must continue to conform to QSRs after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with QSRs. The FDA may withdraw product approvals or recommend product recalls if a company fails to comply with regulatory requirements. The FDA has the authority to conduct mandatory recalls, but that authority is rarely used.

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

We have received 510(k) premarket clearances from the FDA to market our excimer laser and catheter systems for treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma, and vascular blockages resulting from lower extremity vascular disease. We expect to file additional 510(k) submissions for other diseases including, but not limited to, CAD, alopecia areata, and oral lichen planus in the future.

Radiation Emitting Products

For all radiation emitting devices, additional requirements apply under the Electronic Product Radiation Control Provisions of the FDC Act. Electronic product radiation means (i) any ionizing, or non-ionizing electromagnetic or particulate radiation, or (ii) any sonic, infrasonic, or ultrasonic wave emitted from an electronic product as the result of the operation of an electronic circuit in the product. The additional regulations on these products are intended to protect the public from hazardous or unnecessary radiation exposure emitted by these products. These requirements include compliance with applicable radiation safety performance standards and additional reporting to the FDA. The performance standards for lasers include specific user labeling requirements, radiation limitations, and technological requirements for certain safety features.

Non U.S. Regulatory

We have additional clearances from China, from both the CFDA and State Food and Drug Administration, or sFDA, and Korea, from the KFDA. In addition, we also received CE mark for the Pharos dermatological and DABRA vascular system in the third quarter of 2016, enabling our product

launch in Europe. The FDA clearances and the CE mark also allow us to sell these products in other large markets.

Other Healthcare Laws

Our business operations and current and future arrangements with healthcare professionals, consultants, customers and patients, expose us to broadly applicable state and federal fraud and abuse and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- in addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report

annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities may conclude that some of our business practices, including our promotional activities and interactions with our customers do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, additional integrity reporting and oversight obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

International Laws

In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

U.S. Healthcare Reform

In the U.S. and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the U.S., in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers. Among the ACA's provisions of importance to our business are the following:

- implementation of a 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, which, due to subsequent legislation will not go into effect until January 1, 2020;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs.

Employees

As of June 30, 2018, we had 75 full-time employees. Our ability to manage growth effectively will require us to continue to implement and improve our management systems, recruit and train new employees and select qualified independent contractors. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Facilities

We entered into a ten year lease agreement for our new corporate headquarters, which includes our manufacturing facility, located at 2070 Las Palmas Drive, Carlsbad, California 92011 on August 17, 2017. This lease term began on January 1, 2018 and will expire on December 31, 2027. This property consists of approximately 32,000 square feet that will allow for anticipated growth for the foreseeable future and for us to maintain our employees under one roof. We are currently operational in this facility.

We have invested in our manufacturing facility, including making upgrades to our controlled environments by increasing the total square footage from approximately 500 square feet to approximately 2,000 square feet. This provides an adequate work area for fabricating sterile, high quality catheters for the DABRA laser systems and high-reliability laser pump chambers to support both the dermatology and the vascular markets. We have further invested in capital equipment and staff, and believe that our current manufacturing capacity will be sufficient to meet the current expected demand for our products for at least the next 12 months. We believe our existing facility is capable of producing 400 lasers per year and 70,000 catheters per year.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business, financial condition, and results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the names, ages, and positions of our executive officers and directors as of July 13, 2018:

Name	Age	Position
Executive Officers		
Dean Irwin	56	Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors
Andrew Jackson[1]	49	Chief Financial Officer and Secretary
Jeffrey Kraws	54	Co-President
Melissa Burstein, M.B.A.	43	Executive Vice President, and Director
Directors		
Dean Irwin	56	Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors
Melissa Burstein, M.B.A.	43	Executive Vice President, and Director
Richard Heymann[2]	63	Director of Corporate Strategy and Business Development and Director
Martin Burstein, M.B.A.[2]	71	Director
Maurice Buchbinder, M.D.	65	Director
Martin Colombatto	60	Director
Richard Mejia, Jr.[6]	70	Director

(1) Mr. Jackson joined us as chief financial officer in April 2018 and was appointed as secretary in July 2018. Prior to April 2018, Daniel Sanchez-Linares served as our acting chief financial and principal financial officer.
(2) Mr. Burstein and Mr. Heymann each intend to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement to which this prospectus forms a part.
(3) Member of the audit committee
(4) Member of the compensation committee
(5) Member of the nominating and corporate governance committee
(6) Mr. Mejia joined our board of directors in July 2018.

Executive Officers

Dean Irwin founded Ra Medical in 2002 and has served as Chief Executive Officer, Chief Technology Officer and Chairman of the Board since September 2002 and as Co-President since May 2018. Prior to forming Ra Medical, Mr. Irwin was Vice President of Research, Development, and Engineering at PhotoMedex, Inc., a manufacturer of excimer lasers, from February 1998 to August 2002. Prior to his tenure at PhotoMedex, Inc., Mr. Irwin provided scientific consulting for Intel Corporation from January of 1999 to August 1999 and was Vice President of Engineering and General Manager at SpatiaLight, Inc., a manufacturer and seller of high-resolution liquid crystal on silicon microdisplays, from June 1993 to February 1998. Mr. Irwin was also a founder and Chief Scientist at DIR Corp., a custom equipment development company, from May 1985 to January 1991. Mr. Irwin has held various engineering positions with Acculase, Inc., a laser development company, (acquired by PhotoMedex), General Atomics, a defense contractor, and Universal Voltronics Corp., a developer of high voltage power supplies. We believe that Mr. Irwin is qualified to serve as a member of our board of directors due to his senior management roles in multiple companies in the medical devices industry and his deep understanding of our business, operations, and strategy.

Andrew Jackson has served as our Chief Financial Officer since April 2018 and as our Secretary since July 2018. From October 2016 to April 2018 he was Chief Financial Officer for AltheaDx, Inc, a molecular diagnostics company specializing in precision medicine. From March 2014 to March 2016, Mr. Jackson held senior financial positions, including Chief Financial Officer, at Celladon Corporation, a publicly-traded, clinical stage biotechnology company. From April 2013 to March 2014 he held senior financial positions at Sapphire Energy, an industrial biotechnology company. Mr. Jackson received a MSBA in Finance in December 2006 from San Diego State University and a BSB in Accounting in June 1992 from the University of Minnesota.

Jeffrey J. Kraws has served as our Co-President since May 2018 and served as the President of Ra Medical from August 2016 until May 2018. Since 2003, Mr. Kraws has served as Chief Executive Officer and co-founder of Crystal Research Associates and CRA Advisors. Mr. Kraws is a partner at Grannus Securities Pty Ltd. (an Australian based private equity fund) since November 2015. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also served in the treasury group at Bristol-Myers-Squibb Company. Mr. Kraws serves on the board of directors of Avivagen (TSX:VIV), Saleen Automotive, Inc. (OTC: SLNN), and is Chairman of the Board of Synthetic Biologics (NYSE:SYN). Mr. Kraws holds an MBA from Cornell University and a BS degree from State University of New York, Buffalo.

Melissa Burstein co-founded Ra Medical in September of 2002 and has served as its Executive Vice President, and as a Director since September 2002, Ms. Burstein also served as our Secretary from 2002 until 2018. Prior to co-founding Ra Medical, Ms. Burstein held various sales and marketing positions with Eli Lilly and Co., a pharmaceutical company from September of 2001 to March 2003. Ms. Burstein also previously served as Marketing Intern at the Kellogg Company, a consumer packaged goods company from January 2000 to August 2000 and as an Analyst for Sprint International, a telecommunications company from June 1997 to August 1999. Ms. Burstein holds an MBA specializing in international management from Thunderbird, the American Graduate School of International Management, and a B.S. from Georgetown University. We believe that Ms. Burstein is qualified to serve as a member of our board of directors due to her extensive experience in marketing and sales and her deep understanding of our business, operations and strategy.

Directors

Dean Irwin. Please see the biographical information above in the section entitled “Executive Officers.”

Melissa Burstein. Please see the biographical information above in the section entitled “Executive Officers.”

Richard Heymann has served as a director of Ra Medical since July 2008 and as an employee in Corporate Strategy and Business Development since January 2016. Mr. Heymann has served as the President and Chief Executive Officer of Noteworthy Advisors, a real estate, consulting and investment firm since July 2002. Prior to his role at Noteworthy Advisors, Mr. Heymann served as President of Security Financial Bancorp, a real estate, private lender and investment company from 1992 to July 2002. Mr. Heymann attended the University of Wisconsin and holds a B.A. from Idaho

State University. We believe that Mr. Heymann is qualified to serve as a member of our board of directors due to his business acumen and his deep understanding of our company and values. Mr. Heymann intends to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of this registration statement to which this prospectus forms a part.

Martin Burstein has served as a director of Ra Medical since October 2003. Mr. Burstein served as the Vice President of Administration from 2004 to 2012 and the Vice President of Human Resources from 1999 to 2004 for Panasonic Disc Manufacturing Corporation of America, an independently operated subsidiary of Panasonic Corporation of America. He also served as Vice President, Human Resources for Sybase, Inc. from 1997 to 1998, and Director of HR Operations for MFS Communications Company from 1995 to 1997. Mr. Burstein holds an MBA from the University of Missouri. We believe that Mr. Burstein is qualified to serve as a member of our board of directors due to his extensive management experience and his deep understanding of our business and strategy. Mr. Burstein intends to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement to which this prospectus forms a part.

Maurice Buchbinder has served as a director of Ra Medical since January 1, 2017. Dr. Buchbinder has served as Interventional Cardiologist for Maurice Buchbinder M.D., C.M., A Professional Corporation, from October 1994 to present. Dr. Buchbinder holds a Bachelor's of Science degree from McGill University in Montreal, Canada, and a Doctor of Medicine, Master of Surgery, from McGill University. He completed his post-graduate education at Stanford University where he specialized in Cardiovascular Medicine. We believe that Dr. Buchbinder is qualified to serve as a member of our board of directors due to his extensive experience in the medical and medical device industries.

Martin Colombatto has served as a director of Ra Medical since January 2017. Mr. Colombatto has served as a Venture and Industry Partner of Seven Peaks Ventures LLP, a venture capital fund based in Bend, OR, since January 2016. From December 2013 to August 2014, Mr. Colombatto served as a director of PLX Technology, Inc., a technology company. Mr. Colombatto has also served as the Chief Executive Officer and President of Staccato Communications, Inc., an Ultra Wideband semiconductor company, from January 2006 to March 2009 and as Executive Chairman of Staccato Communications, Inc., from January 2006 to September 2010. Prior to joining Staccato, Mr. Colombatto served as Vice President and General Manager of the Networking Business unit of Broadcom Corp., a broadband communication semiconductor company, from July 1996 to July 2002. Mr. Colombatto was also previously employed by LSI Logic, an application specific semiconductor company, from August 1987 to July 1996. Mr. Colombatto also previously held engineering positions at Reliance Electric, a production automation and control company, from August 1985 to June 1987 and Texas Instruments, an electronics company, from June 1982 to April 1985. Mr. Colombatto holds a Bachelor's of Science Degree in Electronic Engineering Technology from California State Polytechnic University, Pomona. We believe that Mr. Colombatto is qualified to serve as a member of our board of directors due to his extensive management experience and familiarity with our business and strategy.

Richard Mejia, Jr. has served as a director of Ra Medical since July 2018. Mr. Mejia previously served as a partner in the San Diego office of Ernst & Young LLP, a public accounting firm, from 1988 up until his retirement in 2008, including that from 2001 through 2008 he led the Life Sciences practice. Mr. Mejia currently serves as a member of the board of directors of SkyBell Technologies, Inc., a technology company. From 2014 to 2018 he served on the Board of Stemedica Cell Technologies, Inc., a life science company and from 2008 to 2015, Mr. Mejia served on the board of directors of Dot Hill Systems Corp., a public company which manufacturers software and hardware storage systems. From 2010 to 2012 he served on the board of directors of Sharp Health, a healthcare delivery system. Mr. Mejia holds a B.S. in Accounting from the University of Southern California. We believe that Mr. Mejia is qualified to serve as a director because of his extensive experience in public accounting, financial matters, industry knowledge and serving on boards of directors.

Board Composition and Risk Oversight

Our business and affairs are managed under the direction of our board of directors. The number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering. Our board of directors currently consists of seven (7) directors, of whom will qualify as "independent" under New York Stock Exchange, or NYSE, listing standards, including . Mr. Burstein and Mr. Heymann intend to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement to which this prospectus forms a part. Prior to the completion of this offering, we intend to appoint at least additional directors, who are expected to be "independent" under the rules of the NYSE and the Exchange Act, to our board of directors so that our board will be composed of directors and meet the independence requirements and other applicable requirements of the New York Stock Exchange.

Following the completion of this offering, our amended and restated certificate of incorporation and our amended and restated bylaws will provide that, immediately following the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows:

- the Class I directors will be , , and , and their terms will expire at the annual meeting of stockholders to be held in 2019;
- the Class II directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2020; and
- the Class III directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2021.

Upon expiration of the term of a class of directors, directors for that class will be elected for three-year terms at the annual meeting of stockholders in the year in which that term expires. Each director's term shall continue until the election and qualification of his or her successor, or his or her earlier death, resignation or removal. Any additional directorships resulting from an increase in the number of authorized directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control. Under Delaware law, our directors may be removed for cause by the affirmative vote of the holders of a majority of our outstanding voting stock. Directors may not be removed by our stockholders without cause. See "*Description of capital stock—anti-takeover effects of Delaware law and our certificate of incorporation and bylaws*" for a discussion of these and other anti-dilution provision found in our amended and restated certificate of incorporation.

Director Independence

Upon the completion of this offering, we anticipate that our common stock will be approved for listing on the NYSE. Under the rules of the NYSE, independent directors must comprise a majority of a listed company's board of directors within a specified period of the completion of its initial public offering. In addition, the rules of the NYSE require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the NYSE, a director will only qualify as an "independent director" if,

in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Messrs. representing of our seven (7) directors, is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of the NYSE. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section captioned "*—Certain relationships and related party transactions*."

Our co-founders, Dean Irwin, currently serving as our Chief Executive Officer, Co-President, Chief Technology Officer and Chairman of the board of directors, and Melissa Burstein, currently serving as our Executive Vice President, and a member of our board of directors, are married. Additionally, Martin Burstein, currently serving as a member of our board of directors, is Ms. Burstein's father and Mr. Irwin's father-in-law. Other than the relationships described above, none of our directors or officers has a family relationship with any other director or officer.

Lead Independent Director

Our board of directors has adopted corporate governance principles that provide that one of our independent directors should serve as our Lead Independent Director at any time when our Chief Executive Officer serves as the Chairman of our board of directors or if the Chairman is not otherwise independent. Because Dean Irwin is our Chairman and is not an "independent" director as defined in the listing standards of the NYSE, our board of directors has appointed to serve as our Lead Independent Director. As Lead Independent Director, will preside over periodic meetings of our independent directors, serve as a liaison between our Chairman and our independent directors, and perform such additional duties as our board of directors may otherwise determine and delegate.

Board Committees

Prior to the completion of this offering, our board of directors will establish an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will be comprised and will have the responsibilities described below. Each of the below committees will have a written charter approved by our board of directors. Each of the committees will report to our board of directors as such committee deems appropriate and as our board of directors may request. Upon completion of this offering, copies of each charter will be posted on the investor relations section of our website.

Audit Committee

Our audit committee will be comprised of , , and . will serve as the chairperson of our audit committee. Our board of directors has determined that each member of our audit committee meets the requirements for independence and financial literacy under the applicable rules and regulations of the SEC and the listing standards of the NYSE. Our board of directors has also determined that is an "audit committee financial expert" as defined in the rules of the SEC and has the requisite financial sophistication as defined under the listing standards of the NYSE. The responsibilities of our audit committee will include, among other things:

- selecting and hiring the independent registered public accounting firm to audit our financial statements;
- overseeing the performance of the independent registered public accounting firm and taking those actions as it deems necessary to satisfy itself that the accountants are independent of management;
- reviewing financial statements and discussing with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews, and the reports and certifications regarding internal control over financial reporting and disclosure controls;
- preparing the audit committee report that the SEC requires to be included in our annual proxy statement;
- reviewing the adequacy and effectiveness of our internal controls and disclosure controls and procedures;
- overseeing our policies on risk assessment and risk management;
- reviewing related party transactions; and
- approving or, as required, pre-approving, all audit and all permissible non-audit services and fees to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, which satisfies the applicable rules and regulations of the SEC and the listing standards of the NYSE.

Compensation Committee

Our compensation committee will be comprised of , , and . will serve as the chairperson our compensation committee. Our board of directors has determined that each member of our compensation committee meets the requirements for independence under the applicable rules and regulations of the SEC and listing standards of the NYSE. Each member of the compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. The purpose of our compensation committee will be to oversee our compensation policies, plans and benefit programs and to discharge the responsibilities of our board of directors relating to compensation of our executive officers. The responsibilities of our compensation committee will include, among other things:

- reviewing and approving or recommending to the board for approval compensation of our executive officers and directors;
- overseeing our overall compensation philosophy and compensation policies, plans and benefit programs for service providers, including our executive officers;

- reviewing, approving and making recommendations to our board of directors regarding incentive compensation and equity plans; and
- administering our equity compensation plans.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, which satisfies the applicable rules and regulations of the SEC and the listing standards of the NYSE.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will be comprised of , , and . will serve as the chairperson of our nominating and corporate governance committee. Our board of directors has determined that all members of our nominating and corporate governance committee meet the requirements for independence under the applicable rules and regulations of the SEC and listing standards of the NYSE. The responsibilities of our nominating and corporate governance committee will include, among other things:

- identifying, evaluating and selecting, or making recommendations to our board of directors regarding, nominees for election to our board of directors and its committees;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees; and
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters.

Our nominating and corporate governance committee will operate under a written charter, to be effective prior to the completion of this offering, which satisfies the applicable rules and regulations of the SEC and the listing standards of the NYSE.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

Director Compensation

As of December 31, 2017, none of our non-employee directors held any outstanding equity awards to purchase shares of our common stock. We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees.

The following table presents information concerning each grant of an award made to our non-employee directors under our Compensation Plan subsequent to December 31, 2017:

Name	Principal Position	Grant Date	Shares Subject to Stock Options	Shares Subject to Restricted Stock Units
Martin Burstein	Director	June 4, 2018	42,000(1)	—
		June 4, 2018	150,000(2)	—
		June 8, 2018	—	30,390(3)
		June 8, 2018	—	148,860(4)
Martin Colombatto	Director	June 4, 2018	42,000(1)	—
		June 8, 2018	—	30,390(3)
Maurice Buchbinder	Director	June 4, 2018	42,000(1)	—
		June 8, 2018	—	30,390(3)

(1) One thirty-sixth of the shares subject to the option vest each month over the thirty six months following January 1, 2017, on the same day of the month, subject to the director's continued service. In the event of a Change in Control (as defined in the Compensation Plan), one hundred percent (100%) of the shares subject to the option shall immediately vest.

(2) One-third of the shares subject to the option shall vest on the one year anniversary of the date of grant and one thirty-sixth of the shares subject to the option shall vest monthly thereafter, subject to the director's continued service.

(3) Thirty-three percent (33%) of the restricted stock units shall vest on the 10th day of the third month following the expiration of the Lock-Up Period (as defined in the award agreement), thirty-three percent (33%) of the restricted stock units shall vest on the 15th day of the sixth month following the expiration of the Lock-Up Period, and thirty-four (34%) of the restricted stock units shall vest on the 20th day of the ninth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

(4) Fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the first month following the expiration of the Lock-Up Period (as defined in the award agreement), fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the second month following the expiration of the Lock-Up Period, fifteen percent (15%) of the Restricted Stock Units shall vest on the 15th day of the fourth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 15th day of the fifth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the seventh month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the eighth month following the expiration of the Lock-Up Period, and ten percent (10%) of the restricted stock units shall vest on the 25th day of the tenth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

The following table sets forth information concerning compensation paid or accrued for services rendered to us by members of our board of directors for the year ended December 31, 2017. Mr. Irwin and Ms. Burstein are executive officers and did not receive any additional compensation for their services as directors. Information concerning the compensation earned by Mr. Irwin and Ms. Burstein is set forth in the section captioned "Executive compensation." Mr. Heymann is a non-executive employee of the Company, but has been included below. Additionally, the table excludes Richard Mejia Jr., who was appointed to our board of directors in 2018.

Name	Fees Earned or Paid in Cash ($)	All Other Compensation ($)	Total ($)
Maurice Buchbinder, M.D.	$ 2,000	$	$ 2,000
Martin Burstein, M.B.A.	$ 2,000	—	$ 2,000
Martin Colombatto	$ 2,000	—	$ 2,000
Richard Heymann	—	$ 36,000(1)	$36,000

(1) Mr. Heymann received $36,000 for services provided to us in 2017 as a part-time employee of our company. He did not receive any additional compensation as a member of our board of directors.

Non-Employee Director Compensation Policy

We have retained Compensia, a national compensation consultant, to provide our board of directors with an analysis of market data compiled from certain comparable public companies and assistance in determining compensation of directors following this offering. Our board of directors has adopted our Outside Director Compensation Policy that will be effective upon the effective date of the registration statement of which this prospectus forms a part. Our Outside Director Compensation Policy will provide that all non-employee directors will be entitled to receive the following cash compensation for their services following the completion of the offering contemplated by this prospectus:

- $40,000 retainer per year for each non-employee director;
- $40,000 retainer per year for service as chairman of the board of directors;
- $30,000 retainer per year for service as lead non-employee director;
- $20,000 retainer per year for the chairman of the audit committee or $10,000 retainer per year for each other member of the audit committee;
- $15,000 retainer per year for the chairman of the compensation committee or $7,000 retainer per year for each other member of the compensation committee; and
- $8,500 retainer per year for the chairman of the nominating and corporate governance committee or $4,500 retainer per year for each other member of the nominating and corporate governance committee.

In addition to the cash compensation structure described above, our Outside Director Compensation Policy will provide the following equity incentive compensation program for non-employee directors. Each non-employee director who first joins us (other than a director who becomes a non-employee director as a result of terminating employment with us) automatically will be granted on the first trading date on or after his or her start date as a non-employee director a one-time, initial restricted stock unit award with a value of $140,000. Further, on the date of each of our annual stockholder meetings following the effective date of the registration statement of which this prospectus forms a part, each non-employee director who is continuing as a director following our annual stockholder meeting automatically will be granted an annual restricted stock unit award with a value of $100,000. Unless otherwise determined by our board of directors or our compensation committee, the number of restricted stock units subject to such awards will be determined based on the per share fair market value of our common stock on the applicable grant date. Each initial restricted stock unit award will vest as to 1/3rd of the award on each of the first three anniversaries of the date the director's service as a non-employee director started, subject to continued service through each relevant vesting date. Each annual restricted stock unit award will vest as to 100% of the underlying shares on the earlier of the one-year anniversary of the award's grant date or the day before the date of our annual stockholder meeting next following the award's grant date, subject to continued service through such date. In the event of a change in control of our company, all equity awards granted to a non-employee director (including those granted pursuant to our Outside Director Compensation Policy) will fully vest and become immediately exercisable, subject to continued service through such date.

In any fiscal year, a non-employee director may be paid, issued or granted cash compensation and equity awards with a total value of no greater than $500,000 (with the value of an equity award based on its grant date fair value for purposes of this limit), or the annual director limit. Equity awards or cash compensation granted to a non-employee director while he or she was an employee or consultant (other than a non-employee director) will not count toward the annual director limit.

Our Outside Director Compensation Policy will also provide for the reimbursement of our non-employee directors for reasonable, customary and documented travel expenses to attend meetings of our board of directors and committees of our board of directors.

Compensation for our non-employee directors is not limited to the equity awards and payments set forth in our Outside Director Compensation Policy. Our non-employee directors will remain eligible to receive equity awards and cash or other compensation outside of the Outside Director Compensation Policy, as may be provided from time to time at the discretion of our board of directors. For further information regarding the equity compensation of our non-employee directors, see the section of this prospectus titled "*Executive compensation-Employee Benefit and Stock Plans—2018 Equity Incentive Plan*."

Code of Ethics and Conduct

Our board of directors has adopted a written code of ethics and conduct, effective upon completion of this offering, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and agents and representatives, including consultants. Following the completion of this offering, a copy of the code of ethics and conduct will be available on our website at www.ramed.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2017, which consisted of our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, are: Dean Irwin, Jeffrey Kraws, and Melissa Burstein.

2017 Summary Compensation Table

The following table provides information regarding the compensation of our named executive officers during the year ended December 31, 2017.

Name and Principal Position[1]	Year	Salary ($)	Bonus ($)	All Other Compensation ($)	Total ($)
Dean Irwin Chief Executive Officer and Co-President	2017	231,500	—	—	231,500
Jeffrey Kraws Co-President	2017	150,000	120,000[2]	—	270,000
Melissa Burstein. Executive Vice President	2017	163,900	—	28,600[3]	192,500

(1) Titles and capacities are listed as of July 13, 2018.
(2) This amount represents a discretionary bonus earned in 2017 and paid to Mr. Kraws in 2018.
(3) This amount includes $6,000 for a car allowance to Ms. Burstein and $22,580 for a health insurance plan paid by us on behalf of Ms. Burstein. Mr. Irwin, Ms. Burstein's spouse, is covered by Ms. Burstein's health insurance plan.

Outstanding Equity Awards at December 31, 2017

There were no outstanding equity awards at December 31, 2017.

Subsequent Events

In June 2018, our board of directors approved a $340,000 discretionary bonus to Ms. Burstein for additional contributions in connection with preparing for our initial public offering. This bonus was paid, less applicable withholdings, on June 30, 2018.

In June 2018, our board of directors approved grants to certain officers, directors, employees, consultants and other service providers of (i) options to purchase an aggregate of 1,901,900 shares of our common stock at an exercise price of $28.94 per share; and (ii) restricted stock units with respect to an aggregate of 1,340,832 shares of our common stock. For award recipients other than directors, one-third of the shares subject to the options vest on the one year anniversary of the date of grant and one thirty-sixth of the shares subject to the options vest monthly thereafter, subject to the award recipient's continued service. For directors, the options vest monthly over thirty-six months following the vesting commencement date of January 1, 2017, subject to such director's continued service. The restricted stock units are scheduled to vest at various times commencing the day following the expiration of the lock-up until 10 months following the expiration of the lockup period.

The following table presents information concerning each grant of an equity award made to a named executive officer under our Compensation Plan:

Name	Principal Position	Grant Date	Shares Subject to Stock Options	Shares Subject to Restricted Stock Units
Dean Irwin	Chief Executive Officer	June 4, 2018	250,000(1)	—
		June 8, 2018	—	248,100(2)
Andrew Jackson	Chief Financial Officer and Secretary	June 4, 2018	290,000(1)	—
		June 8, 2018	—	39,482(3)
Jeffrey Kraws	Co-President	June 4, 2018	255,000(1)	—
		June 8, 2018	—	175,647(4)
		June 8, 2018	—	6,807(3)
Melissa Burstein	Executive Vice President	June 4, 2018	150,000(1)	—
		June 8, 2018	—	148,860(2)

(1) One-third of the shares subject to the option shall vest on the one year anniversary of the date of grant and one thirty-sixth of the shares subject to the option shall vest monthly thereafter, subject to the officer's continued service. If the officer's employment with the Company is terminated by the Company without cause, one-hundred percent (100%) of the shares subject to the option that have not vested shall immediately vest.

(2) Fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the first month following the expiration of the Lock-Up Period (as defined in the award agreement), fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the second month following the expiration of the Lock-Up Period, fifteen percent (15%) of the Restricted Stock Units shall vest on the 15th day of the fourth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 15th day of the fifth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the seventh month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the eighth month following the expiration of the Lock-Up Period, and ten percent (10%) of the restricted stock units shall vest on the 25th day of the tenth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

(3) Thirty-three percent (33%) of the restricted stock units shall vest on the 10th day of the third month following the expiration of the Lock-Up Period (as defined in the award agreement), thirty-three percent (33%) of the restricted stock units shall vest on the 15th day of the sixth month following the expiration of the Lock-Up Period, and thirty-four (34%) of the restricted stock units shall vest on the 20th day of the ninth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

(4) Twenty-five percent (25%) of the restricted stock units shall vest on the 10th day of the third month following the expiration of the Lock-Up Period (as defined in the award agreement), twenty-five percent (25%) of the restricted stock units shall vest on the 15th day of the fourth month following the expiration of the Lock-Up Period, twenty-five percent (25%) of the restricted stock units shall vest on the 15th day of the fifth month following the expiration of the Lock-Up Period, and twenty-five percent (25%) of the restricted stock units shall vest on the 15th day of the sixth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

Employment Arrangements with Our Executive Officers

Dean Irwin

We entered into a confirmatory employment letter with Mr. Irwin, our Chief Executive Officer, Co-President and Chief Technology Officer, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Mr. Irwin's annual base salary will be $418,000 and Mr. Irwin will be eligible annually for a target cash bonus of 100% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Irwin is also eligible for severance benefits, as more fully described in "*Management— Executive Change in Control and Severance Agreements*."

Andrew Jackson

We entered into a confirmatory employment letter with Mr. Jackson, our Chief Financial Officer and Secretary, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Mr. Jackson's annual base salary will be $348,000 and Mr. Jackson will be eligible annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Jackson is also eligible for severance benefits, as more fully described in "*Management— Executive Change in Control and Severance Agreements*."

Jeffrey Kraws

We entered into a confirmatory employment letter with Mr. Kraws, our Co-President, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Mr. Kraws' annual base salary will be $287,000 and Mr. Kraws will be eligible annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Kraws is also eligible for severance benefits, as more fully described in *"Management— Executive Change in Control and Severance Agreements."*

Melissa Burstein

We entered into a confirmatory employment letter with Ms. Burstein, our Executive Vice President, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Ms. Burstein's annual base salary will be $308,000 and Ms. Burstein will be eligible annually for a target cash bonus of 50% of her annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Ms. Burstein is also eligible for a car allowance equal to $500 a month, less applicable tax withholdings. Ms. Burstein is also eligible for severance benefits, as more fully described in *"Management— Executive Change in Control and Severance Agreements."*

Executive Change in Control and Severance Agreements

Our board of directors has approved a change in control and severance agreement for each of our executive officers, including our named executive officers, which agreements provide for certain severance and change in control benefits as described below. Each change in control and severance agreement supersedes any prior agreement or arrangement the executive officer may have had with us that provides for severance and/or change in control payments or benefits.

Each change in control and severance agreement has an initial term of three years, starting on the effective date of the agreement, the closing of our initial public offering. On the third anniversary of the effective date of the agreement, the agreement will renew automatically for additional one year terms unless either party provides the other party with written notice of nonrenewal at least one year prior to the date of automatic renewal. However, if a change in control (as defined in the applicable agreement) occurs when there are fewer than 12 months remaining during the initial term or during an additional term, the term of the change in control and severance agreement will extend automatically through the date that is 12 months following the date of the change in control.

If an executive officer's employment is terminated outside the period beginning 3 months before a change in control and ending 12 months (or 18 months in the case of Mr. Irwin) following a change in control, or the Change in Control Period either (1) by the Company (or any of its subsidiaries) without "cause" (excluding

by reason of death or disability) or (2) by the executive officer for "good reason" (as such terms are defined in the executive officer's change in control and severance agreement), the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to 12 months of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction); and
- payment of premiums for coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, for the executive officer and the executive officer's eligible dependents, if any, for up to 12 months, or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law.

If, within the Change in Control Period, the executive officer's employment is terminated either (1) by the Company (or any of its subsidiaries) without cause (excluding by reason of death or disability) or (2) by the executive officer for good reason, the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to 12 months (or 18 months in the case of Mr. Irwin) of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction) or if greater, at the level in effect immediately prior to the change in control);
- a lump-sum payment equal to 100% (or 150% in the case of Mr. Irwin) of the executive officer's target annual bonus as in effect for the fiscal year in which such termination occurs;
- payment of premiums for coverage under COBRA for the executive officer and the named executive officer's eligible dependents, if any, for up to 12 months (or 18 months in the case of Mr. Irwin), or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law; and
- 100% accelerated vesting and exercisability of all outstanding equity awards and, in the case of an equity award with performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at target.

If any of the amounts provided for under these change in control and severance agreements or otherwise payable to our named executive officers would constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code and could be subject to the related excise tax, the executive officer would be entitled to receive either full payment of benefits under his or her change in control or severance agreement or such lesser amount which would result in no portion of the benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the executive officer. The change in control and severance agreements do not require us to provide any tax gross-up payments.

Employee Benefit and Stock Plans

2018 Equity Incentive Plan

Prior to the completion of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our 2018 Equity Incentive Plan, or our 2018 Plan. We expect that our 2018 Plan will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our 2018 Plan will provide for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, or Code, to our

employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

Authorized Shares. A total of shares of our common stock will be reserved for issuance pursuant to our 2018 Plan. In addition, the shares reserved for issuance under our 2018 Plan will also include (1) those shares reserved but unissued under our Compensation Plan (as defined below) as of the date of stockholder approval of the 2018 Plan and (2) shares of our common stock subject to or issued pursuant to awards granted under our Compensation Plan that, after the date of stockholder approval of the 2018 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2018 Plan pursuant to (1) and (2) is shares). The number of shares available for issuance under our 2018 Plan will also include an annual increase on the first day of each fiscal year beginning with our fiscal year, equal to the least of:

- shares;
- percent (%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by us due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2018 Plan (unless the 2018 Plan has terminated). With respect to stock appreciation rights, only the net shares actually issued will cease to be available under the 2018 Plan and all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2018 Plan (unless the 2018 Plan has terminated). Shares that have actually been issued under the 2018 Plan will not be returned to the 2018 Plan, except if shares issued pursuant to awards of restricted stock, restricted stock units, performance shares or performance units are repurchased by or forfeited to us, such shares will become available for future grant under the 2018 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under the 2018 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2018 Plan.

Plan Administration. Our board of directors or one or more committees appointed by our board of directors will administer our 2018 Plan. The compensation committee of our board of directors is expected to administer our 2018 Plan. In addition, if we determine it is desirable to qualify transactions under our 2018 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2018 Plan, the administrator has the power to administer our 2018 Plan and make all determinations deemed necessary or advisable for administering the 2018 Plan, including but not limited to, the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2018 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions, and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2018 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2018 Plan, including creating sub-plans, modify or

amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except no option or stock appreciation right will be extended past its original maximum term), and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash, or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Stock Options. Stock options may be granted under our 2018 Plan. The exercise price of options granted under our 2018 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any parent or subsidiary of ours) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for 3 months following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2018 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2018 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding ten years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for 3 months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2018 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2018 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2018 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its

sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of shares of restricted stock will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2018 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2018 Plan, the administrator determines the terms and conditions of restricted stock units, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2018 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance objectives established by the administrator are achieved or the awards otherwise vest. The administrator will establish performance objectives or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number or the value of performance units and performance shares to be paid out to participants. The administrator may set performance objectives based on the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance units or performance shares. Performance units will have an initial value established by the administrator on or prior to the grant date. Performance shares will have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may payout earned performance units or performance shares in cash, shares or in some combination thereof.

Outside Directors. All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2018 Plan. To provide a maximum limit on the cash compensation and equity awards that can be made to our outside directors, our 2018 Plan provides that in any given fiscal year, an outside director will not be granted cash compensation and equity awards with an aggregate value greater than $ (with the value of each equity award based on its grant date fair value as determined according to U.S. GAAP). Any cash compensation paid or awards granted to an individual for his or her services as an employee or consultant (other than as an outside director) will not count toward this limit.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2018 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments. In the event of any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of our shares or other securities, or other change in our corporate structure affecting our shares, to prevent diminution or enlargement of the benefits or potential benefits available under our 2018 Plan, the administrator will adjust the number and class of shares that may be delivered under our

2018 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2018 Plan.

Dissolution or Liquidation. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. Our 2018 Plan provides that in the event of a merger or change in control, as defined under our 2018 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant or all awards of the same type similarly.

If a successor corporation does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not assumed or substituted in the event of a change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, in the event of a change in control, the outside director will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

Clawback. Awards will be subject to any clawback policy of ours, and the administrator also may specify in an award agreement that the participant's rights, payments, and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture, and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment; Termination. The administrator has the authority to amend, alter, suspend or terminate our 2018 Plan, provided such action does not materially impair the rights of any participant. Our 2018 Plan automatically will terminate in 2028, unless we terminate it sooner.

2018 Stock Compensation Plan

Our 2018 Stock Compensation Plan, or the Compensation Plan, was adopted by our board of directors and approved by our stockholders in June 2018.

The Compensation Plan permits the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any of our parent and subsidiary corporation's employees, and the grant of nonstatutory stock options, stock appreciation rights, restricted stock, and restricted stock units to our employees, consultants and directors and any of our parent and subsidiary corporation's employees and consultants. The Compensation Plan will be terminated prior to the completion of this

offering, and thereafter we will not grant any additional awards under the Compensation Plan. However, the Compensation Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the Compensation Plan.

Authorized Shares. As of July 13, 2018, the maximum aggregate number of shares of our common stock authorized for issuance under the Compensation Plan was 3,300,000 shares, of which 70,278 shares were available for grant as of July 13, 2018. Shares may be authorized but unissued, or reacquired common stock. Shares issued pursuant to awards granted under our Compensation Plan that expire or become unexercisable without having been exercised in full, are surrendered under an exchange program, or are forfeited to or repurchased by us due to the failure to vest, as well as shares used to pay the exercise price of an award or to satisfy the tax withholdings related to an award, will become available for future grant under the Compensation Plan while the Compensation Plan remains in effect. In addition, to the extent that an award is paid out in cash rather than shares, such cash payment will not reduce the number of shares available for issuance under the Compensation Plan. Further, only shares actually issued under stock appreciation rights will reduce the shares available for issuance under the Compensation Plan.

As of July 13, 2018, options to purchase 1,892,000 shares of our common stock and restricted stock units covering 1,377,722 shares of our common stock were outstanding under the Compensation Plan.

Plan Administration. Our Compensation Plan is administered by our board of directors or a committee appointed by it. Subject to the provisions of our Compensation Plan, the administrator has the power to construe and interpret our Compensation Plan and any awards granted under it, determine the fair market value of our common stock, determine the recipients of awards, approve award agreements for use under the Compensation Plan, and determine the terms of awards, including, the number of shares subject to each award, the exercise price, the time or times at which awards may be exercised, and any vesting acceleration. The administrator may amend awards as well as implement a program under which (1) outstanding awards are surrendered or cancelled in exchange for awards of the same type (which may have higher or lower exercise prices and different terms), awards of a different type, or cash, (2) award holders have an opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, or (3) the exercise price of an outstanding award is increased or reduced. The administrator may establish rules and regulations related to the Compensation Plan, including sub-plans for satisfying applicable foreign laws or qualifying for favorable tax treatment under applicable foreign laws.

Stock Options. Prior to the completion of this offering, we may grant options under our Compensation Plan. The exercise price per share of all options must equal at least 100% of the fair market value per share of our common stock on the grant date. The term of an option may not exceed ten years. An incentive stock option to be granted to a participant who owns more than 10% of the total combined voting power of all classes of our stock or any of our parent or subsidiary corporations may not have a term in excess of five years and must have a per share exercise price of at least 110% of the fair market value per share of our common stock on the grant date. After the termination of service of an employee, director or consultant due to death or disability, his or her option will remain exercisable for 6 months (or such longer period of time specified in the option agreement) following the termination of service. In all other cases, the option will remain exercisable for 30 days following a termination of service (or such longer period of time specified in the option agreement). An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of the Compensation Plan, the administrator determines all other terms of options, including vesting and the method of payment of the exercise price of an option.

Stock Appreciation Rights. Prior to the completion of this offering, we may grant stock appreciation rights under our Compensation Plan. Stock appreciation rights allow the recipient to receive the

appreciation in the fair market value of our common stock between the grant date and the exercise date. The per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share of our common stock on the grant date. The term of a stock appreciation right may not exceed 10 years. Stock appreciation rights are generally subject to the same post-termination exercise period rules as options. Subject to the provisions of our Compensation Plan, the administrator determines all other terms of stock appreciation rights, including when such rights vest and become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination of both.

Restricted Stock. Prior to the completion of this offering, we may grant restricted stock under our Compensation Plan. Restricted stock awards are grants of shares of our common stock that may be subject to various restrictions, including restrictions on transferability and forfeiture provisions. Subject to the terms of our Compensation Plan, the administrator will determine the number of shares of restricted stock granted and other terms and conditions of such awards. The administrator may impose whatever conditions to vesting it determines to be appropriate, and may, in its sole discretion, accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that have not vested are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Prior to the completion of this offering, we may grant restricted stock units under our Compensation Plan. Restricted stock units are bookkeeping entries with each unit representing an amount equal to the fair market value of one share of our common stock. The administrator determines the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. The administrator in its sole discretion may reduce or waive any vesting criteria. The administrator determines in its sole discretion whether restricted stock units will be settled in cash, shares of our common stock, or a combination of both. Restricted stock units that do not vest will be forfeited by the recipient and will return to us.

Non-Transferability of Awards. Unless the administrator provides otherwise, our Compensation Plan generally does not allow for the transfer of awards other than by will or the laws of descent or distribution, and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of our shares or other securities, or other change in our corporate structure affecting our shares, to prevent diminution or enlargement of the benefits or potential benefits to be made available under the Compensation Plan, the administrator will adjust the number and class of shares that may be delivered under our Compensation Plan and/or the number, class, and price of shares covered by each outstanding award. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable prior to the proposed transaction, and to the extent not previously exercised, awards will terminate immediately prior to the closing of the proposed transaction.

Merger or Change in Control. Our Compensation Plan provides that in the event of a merger or change in control, as defined under our Compensation Plan, each outstanding award will be treated as the administrator determines, including, without limitation, that each award will be assumed or a substantially equivalent award substituted by the acquiring or succeeding corporation (or an affiliate thereof). The administrator is not required to treat all awards similarly in the transaction.

If a successor corporation does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock

appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met, in all cases unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant. If an option or stock appreciation right is not assumed or substituted in the event of a change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

Forfeiture Events. Awards will be subject to any clawback policy of ours, and the administrator may specify in an award agreement that the participant's rights, payments, and benefits with respect to an award will be subject to reduction, cancellation, forfeiture, or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and any amounts paid under the award pursuant to the terms of such clawback policy or to comply with applicable laws.

Amendment; Termination. Our board of directors has the authority to amend, alter, suspend or terminate the Compensation Plan, so long as such action does not impair the rights of any participant, unless mutually agreed in writing otherwise between us and the affected participant. The Compensation Plan will be terminated prior to the completion of this offering, and thereafter we will not grant any additional awards under the Compensation Plan. However, the Compensation Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the Compensation Plan.

2018 Employee Stock Purchase Plan

Prior to the completion of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our 2018 Employee Stock Purchase Plan, or our ESPP. We expect that our ESPP will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. We believe that allowing our employees to participate in our ESPP will provide them with a further incentive towards promoting our success and accomplishing our corporate goals.

Authorized Shares. A total of shares of our common stock will be available for sale under our ESPP. The number of shares of our common stock that will be available for sale under our ESPP also includes an annual increase on the first day of each fiscal year beginning with our fiscal year, equal to the least of:

- shares;
- percent (%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as the administrator may determine.

Plan Administration. We expect that the compensation committee of our board of directors will administer our ESPP and will have full and exclusive discretionary authority to construe, interpret and apply the terms of the ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the ESPP, designate our subsidiaries and affiliates as participating in the ESPP, determine eligibility, adjudicate all disputed claims filed under the ESPP and establish procedures that it deems necessary for the administration of the ESPP, including, but not limited to, adopting such procedures and sub-plans as are necessary or appropriate to permit participation in the ESPP by employees who are

foreign nationals or employed outside the United States. The administrator's findings, decisions and determinations are final and binding on all participants to the full extent permitted by law.

Eligibility. Generally, all of our employees will be eligible to participate if they are customarily employed by us, or any participating subsidiary or affiliate, for at least 20 hours per week and more than five months in any calendar year. The administrator, in its discretion, may, prior to an enrollment date, for all options to be granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date, (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator), (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator), (iv) is a highly compensated employee within the meaning of Section 414(q) of the Code or (v) is a highly compensated employee within the meaning of Section 414(q) of the Code with compensation above a certain level or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our ESPP if such employee:

- immediately after the grant would own capital stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of capital stock of ours or of any parent or subsidiary of ours; or
- holds rights to purchase shares of our common stock under all employee stock purchase plans of ours or any parent or subsidiary of ours that accrue at a rate that exceeds $25,000 worth of shares of our common stock for each calendar year in which such rights are outstanding at any time.

Offering Periods. Our ESPP will include a component that allows us to make offerings intended to qualify under Section 423 of the Code and a component that allows us to make offerings not intended to qualify under Section 423 of the Code to designated companies, as described in our ESPP. Our ESPP will provide for offering periods. The offering periods will be scheduled to start on the first trading day on or after and of each year, except the first offering period will start on the first trading day on or after the effective date of the registration statement of which this prospectus forms a part and will end on the last trading day on or before . Each offering period will include purchase periods, which unless the administrator provides otherwise, will (i) start on the first trading day on or after and and (ii) end on the last trading day on or before of the same year and of the following year, respectively, except that the first purchase period under our ESPP will start on the first trading day on or after the effective date of the registration statement of which this prospectus forms a part and will end on the last trading day on or before .

Contributions. Our ESPP will permit participants to purchase shares of our common stock through contributions (in the form of payroll deductions or otherwise to the extent permitted by the administrator) of up to % of their eligible compensation, which includes a participant's base straight time gross earnings but excludes payments for incentive compensation, bonuses, payments for overtime and shift premium, equity compensation income and other similar compensation. Unless otherwise determined by the administrator, a participant may make a one-time decrease (but not increase) to the rate of his or her contributions to 0% during a purchase period.

Exercise of Purchase Right. Amounts contributed and accumulated by the participant will be used to purchase shares of our common stock at the end of each six-month purchase period. A participant may purchase a maximum of shares of our common stock during a purchase period. The purchase price of the shares will be % of the lower of the fair market value of our common stock on the first

trading day of the offering period or on the exercise date. If the fair market value of our common stock on the exercise date is less than the fair market value on the first trading day of the offering period, participants will be automatically withdrawn from such offering period immediately following their purchase of shares of our common stock on the purchase date and will be automatically re-enrolled in the next offering period. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation ends automatically upon termination of employment with us.

Non-Transferability. A participant may not transfer contributions credited to his or her account nor any rights granted under our ESPP other than by will, the laws of descent and distribution or as otherwise provided under our ESPP.

Merger or Change in Control. Our ESPP provides that in the event of a merger or change in control, as defined under our ESPP, a successor corporation (or a parent or subsidiary of the successor corporation) will assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period with respect to which the purchase right relates will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment; Termination. The administrator will have the authority to amend, suspend or terminate our ESPP. Our ESPP automatically will terminate in 2038, unless we terminate it sooner.

Executive Incentive Compensation Plan

Prior to the completion of this offering, our board of directors intends to adopt an Executive Incentive Compensation Plan, or the Bonus Plan. The Bonus Plan will be administered by a committee appointed by our board of directors. Unless and until our board of directors determines otherwise, our compensation committee will be the administrator of the Bonus Plan. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, determined by our compensation committee, based upon performance goals established by our compensation committee. Our compensation committee, in its sole discretion, will establish a target award for each participant under the Bonus Plan, which may be expressed as a percentage of the participant's average annual base salary for the applicable performance period, a fixed dollar amount, or such other amount or based on such other formula as our compensation committee determines to be appropriate.

Under the Bonus Plan, our compensation committee will determine the performance goals applicable to awards, which goals may include, without limitation: attainment of research and development milestones, bookings, business divestitures and acquisitions, cash flow, cash position, contract awards or backlog, customer renewals, customer retention rates from an acquired company, subsidiary, business unit or division, earnings (which may include earnings before interest and taxes, earnings before taxes, and net taxes), earnings per share, expenses, gross margin, growth in stockholder value relative to the moving average of the S&P 500 Index or another index, internal rate of return, market share, net income, net profit, net sales, new product development, new product invention or innovation, number of customers, operating cash flow, operating expenses, operating income, operating margin, overhead or other expense reduction, product defect measures, product release timelines, productivity, profit, retained earnings, return on assets, return on capital, return on equity, return on investment, return on sales, revenue, revenue growth, sales results, sales growth, stock price, time to market, total stockholder return, working capital, and individual objectives such as peer reviews or other subjective or objective criteria. As determined by our compensation committee, the performance goals may be based on generally

accepted accounting principles, or GAAP, or non-GAAP results and any actual results may be adjusted by our compensation committee for one-time items or unbudgeted or unexpected items and/or payments of actual awards under the Bonus Plan when determining whether the performance goals have been met. The goals may be on the basis of any factors our compensation committee determines relevant, and may be on an individual, divisional, business unit, segment or company-wide basis. Any criteria used may be measured on such basis as our compensation committee determines. The performance goals may differ from participant to participant and from award to award. Our compensation committee also may determine that a target award or a portion thereof will not have a performance goal associated with it but instead will be granted (if at all) in the compensation committee's sole discretion.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool. The actual award may be below, at or above a participant's target award, in our compensation committee's discretion. Our compensation committee may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and it will not be required to establish any allocation or weighting with respect to the factors it considers.

Actual awards will generally be paid in cash (or its equivalent) in a single lump sum only after they are earned and approved by our compensation committee. Our compensation committee has the right, in its sole discretion, to settle an actual award with a grant of an equity award under our then-current equity compensation plan, which equity award may have such terms and conditions, including vesting, as our compensation committee determines in its sole discretion. Unless otherwise determined by our compensation committee, to earn an actual award, a participant must be employed by us (or an affiliate of us, as applicable) through the date the actual award is paid. Payment of bonuses occurs as soon as administratively practicable after the end of the applicable performance period, but no later than the dates set forth in the Bonus Plan.

Our board of directors will have the authority to amend or terminate the Bonus Plan provided such action does not alter or impair the existing rights of any participant with respect to any earned actual award without the participant's consent. The Bonus Plan will remain in effect until terminated in accordance with the terms of the Bonus Plan.

Limitations on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective immediately prior to the completion of this offering, will provide that we will indemnify our directors and officers and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Any amendment to, or repeal of, these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission, or claim that occurred or arose prior to that amendment or repeal. If Delaware law is amended to authorize corporate action further eliminating or limiting the

personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into and expect to continue to enter into agreements to indemnify each member of our board of directors and each of our officers. These agreements provide for the indemnification of our directors and officers for certain expenses and liabilities incurred in connection with any action, suit, proceeding or alternative dispute resolution mechanism, or hearing, inquiry or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent or fiduciary of another entity. In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Moreover, a stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

We have obtained insurance policies under which, subject to the limitations of the policies, coverage is provided to our directors and executive officers against losses arising from claims made by reason of breach of fiduciary duty or other wrongful acts as a director or executive officer and to us with respect to payments that may be made by us to these directors and executive officers pursuant to our indemnification obligations or otherwise as a matter of law.

Certain of our non-employee directors may, through their relationships with their employers, be insured and/or indemnified against certain liabilities incurred in their capacity as members of our board of directors.

The underwriting agreement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Emerging Growth Company Status

As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the director and executive officer compensation arrangements and indemnification arrangements discussed above in the sections titled "Management" and "Executive compensation" the following is a description of each transaction since January 1, 2015, and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock, or any immediate family member of or person sharing the household with any of these individuals or entities, had or will have a direct or indirect material interest.

Short Term Loan

In August 2016, Noteworthy Advisors, Inc., a corporation owned by Richard Heymann, a member of our board of directors, loaned us $130,000 pursuant to a short term loan. In September 2016, we repaid $131,300, which was the aggregate outstanding principal and interest of $1,300 due under the loan.

Certain Family Relationships

There are certain relationships between certain of our directors and executive officers. Our co-founders, Dean Irwin, who is currently serving as our Chief Executive Officer, Co-President, Chief Technology Officer and Chairman of the board of directors, and Melissa Burstein, who is currently serving as our Executive Vice President and a member of our board of directors, are married. Additionally, Martin Burstein, who is currently serving as our director, is Ms. Burstein's father and Mr. Irwin's father-in-law.

Policies and Procedures for Transactions with Related Persons

Our audit committee will have the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. The charter of our audit committee that will be in effect upon the completion of this offering will provide that our audit committee shall review and approve or disapprove in advance any related party transaction.

We have adopted a formal written policy, effective upon the completion of this offering, that provides that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our audit committee, or other independent members of our board of directors if it is inappropriate for our audit committee to review such transaction due to a conflict of interest, subject to certain exceptions. Any request for us to enter into a transaction with an executive officer, director, principal stockholder, or any of their immediate family members or affiliates, in which the amount involved exceeds $120,000 must first be presented to our audit committee for review, consideration and approval, subject to certain exceptions. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Transactions with related parties have been disclosed in our financial statements and the related notes, and elsewhere in this prospectus as applicable.

Sales of Securities

The following table sets forth a summary of the sale and issuance of our securities to related persons since January 1, 2015 in which the amount involved exceeded $120,000, other than in connection with compensation arrangements which are described elsewhere in this prospectus under the section captioned "Executive and director compensation." For a description of beneficial ownership of our securities, see the section of this prospectus captioned "Security ownership of certain beneficial owners and management."

Purchaser Name	Shares of Common Stock
Martin Colombatto[1]	37,500

(1) Consists of 37,500 shares of Company common stock issued to M Colombatto Trust in December 2016 at a price of $8.00 per share in exchange for an aggregate cash purchase price of $300,000. Martin Colombatto, the sole trustee of M Colombatto Trust, is a member of our board of directors.

Control by Officers and Directors

Our officers and directors and their affiliates beneficially own, in the aggregate, approximately 62% of our outstanding common stock as of July 13, 2018. As a result, in certain circumstances, these stockholders acting together may be able to determine matters requiring approval of our stockholders, including the election of our directors, or they may delay, defer or prevent a change in control of us. See the section of this prospectus captioned "*Security ownership of certain beneficial owners and management*" below.

Indemnification of Officers and Directors

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law. See the section of this prospectus captioned "*Executive compensation—limitations on liability and indemnification matters*" above.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of July 13, 2018, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors and director nominees; and
- all of our executive officers and directors as a group.

The percentage of beneficial ownership information shown in the table prior to this offering is based on 8,204,851 shares of common stock outstanding as of July 13, 2018, and assumes no participation in this offering by the parties below. The percentage of beneficial ownership shown in the table after this offering is based upon shares of common stock outstanding after the close of this offering, assuming the sale of shares of common stock by us in the offering and no exercise of the underwriters' over-allotment option.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of our common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of July 13, 2018, and restricted stock units that are scheduled to vest within 60 days of July 13, 2018. These shares are deemed to be outstanding and beneficially owned by the person holding those options and restricted stock units for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address of each of the individuals and entities named in the table below is c/o Ra Medical Systems, Inc., 2070 Las Palmas Drive, Carlsbad, California 92011. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

		Percentage	
Name of Beneficial Owner	Shares	Beneficial Ownership Prior to the Offering	Beneficial Ownership After the Offering
Directors, Named Executive Officers, and 5% Stockholders:			
Dean Irwin[1]	2,803,852	34.18%	
Melissa Burstein, M.B.A.[2]	2,803,852	34.18%	
Jeffrey Kraws	—	*	
Martin Burstein, M.B.A.[3]	1,977,833	24.04%	
Richard Heymann[4]	295,011	3.60%	
Maurice Buchbinder, M.D.[5]	25,333	*	
Martin Colombatto[6]	60,833	*	
Richard Mejia, Jr.[7]	—	*	
All directors and executive officers as a group (9 persons)[8]	5,162,862	62.40%	

* Represents beneficial ownership of less than one percent

(1) Consists of 2,803,852 shares held of record by the Dean Irwin and Melissa Burstein Family Trust. Dean Irwin, a member of our board of directors and Named Executive Officer, and Melissa Burstein, a member of our board of directors and Named Executive Officer, each serve as co-trustees of the Dean Irwin and Melissa Burstein Family Trust.

(2) Consists of 2,803,852 shares held of record by the Dean Irwin and Melissa Burstein Family Trust. Dean Irwin, a member of our board of directors and Named Executive Officer, and Melissa Burstein, a member of our board of directors and Named Executive Officer, each serve as co-trustees of the Dean Irwin and Melissa Burstein Family Trust.

(3) Consists of (i) 23,333 shares of common stock subject to options exercisable within 60 days of July 13, 2018; (ii) 1,604,500 shares held of record by Martin Burstein Living Trust dated January 28, 2002 ("M. Burstein Trust"); and (iii) 350,000 shares held of record by Karen Jorgensen Burstein Family Trust Dated November 10, 2000 ("K. Burstein Trust"). Martin Burstein, a member of our board of directors, is a trustee of the M. Burstein Trust. Karen Jorgensen Burstein, Martin Burstein's spouse, is a trustee of the K. Burstein Trust.

(4) Consists of (i) 260,000 shares held of record by Richard Heymann; (ii) 20,000 shares held of record by Heymann Family Trust, of which Mr. Heymann serves as a trustee; (iii) 13,761 shares held of record by Balanced Security Pension Plan FBO Rick Heymann; and (iv) 1,250 shares held of record by Balance Security Pension Plan FBO Christy Heymann Roth, Mr. Heymann's spouse.

(5) Consists of (i) 23,333 shares of common stock subject to options exercisable within 60 days of July 13, 2018; and (ii) 2,000 shares held of record.

(6) Consists of (i) 23,333 shares of common stock subject to options exercisable within 60 days of July 13, 2018; and (ii) 37,500 shares held of record by M. Colombatto Trust. Martin Colombatto, a member of our board of directors, serves as trustee of the M Colombatto Trust.

(7) Mr. Mejia joined our board of directors in July 2018.

(8) Consists of 5,090,863 shares of common stock held and options to purchase 69,999 shares of common stock that are exercisable within 60 days of July 13, 2018.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes certain terms of our capital stock and certain provisions of our amended and restated certificate of incorporation, as they are expected to be in effect immediately prior to the completion of this offering. We expect to adopt an amended and restated certificate of incorporation and amended and restated bylaws in connection with the completion of this offering, and this description summarizes certain of the provisions that are expected to be included in those documents. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which will be filed with the SEC as exhibits to the registration statement of which this prospectus is a part, and to the applicable provisions of Delaware law.

Immediately prior to the completion of this offering, our authorized capital stock will consist of shares of capital stock, of which will be designated as common stock, $0.0001 par value per share, and shares will be designated as preferred stock, $0.0001 par value per share. Our board of directors is authorized, without stockholder approval, except as required by the listing standards of the NYSE, to issue shares of our preferred stock. As of July 13, 2018, there were 8,204,851 shares of common stock issued and outstanding and there were 184 holders of record of our common stock.

Common Stock

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of our stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available. See the section captioned “Dividend Policy” for additional information. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering, our board of directors will have the authority, without further action by the stockholders, to issue from time to time up to shares of preferred stock in one or more series. Our board of directors may designate the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock or delaying, deterring or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

Registration Rights

We have not granted any registration rights.

Anti-Takeover Effects of Delaware law and our Certificate of Incorporation and Bylaws

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws to be effective immediately prior to the completion of this offering will contain provisions that could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions and certain provisions of Delaware law, which are summarized below, may have the effect of discouraging takeover bids, coercive or otherwise. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Issuance of Undesignated Preferred Stock. As discussed above under "Description of Capital Stock—Preferred Stock," our board of directors will have the ability to designate and issue preferred stock with voting or other rights or preferences that could deter hostile takeovers or delay changes in our control or management.

Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting. Our amended and restated certificate of incorporation will provide that our stockholders may not act by written consent. This limit on the ability of stockholders to act by written consent may lengthen the amount of time required to take stockholder actions. As a result, the holders of a majority of our capital stock would not be able to amend the amended and restated bylaws or remove directors without holding a meeting of stockholders called in accordance with the amended and restated bylaws. In addition, our amended and restated bylaws will provide that special meetings of the stockholders may be called only by the chairperson of the board, our chief executive officer or president (in the absence of a chief executive officer) or a majority of our board of directors. A stockholder may not call a special meeting, which may delay the ability of our stockholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors. These advance notice procedures may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed and may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempt to obtain control of our company.

Board Classification. Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve for a three-year term. For more information on the classified board of directors, see "Management—Board of Directors." Our classified board of directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Election and Removal of Directors. Our amended and restated certificate of incorporation and amended and restated bylaws will contain provisions that establish specific procedures for appointing and removing members of our board of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, vacancies and newly created directorships on our board of directors may be filled only by a majority of the directors then serving on the board of directors.

Under our amended and restated certificate of incorporation and amended and restated bylaws, directors may be removed only for cause by the affirmative vote of the holders of a majority of the shares then entitled to vote at an election of directors.

No Cumulative Voting. The Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and amended and restated bylaws will not expressly provide for cumulative voting. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board of directors' decision regarding a takeover.

***Amendment of Charter Provision*.** Any amendment of the above provisions in our amended and restated certificate of incorporation would require approval by holders of at least 66 2/3% of our then outstanding capital stock entitled to vote, voting together as a single class.

Delaware Anti-Takeover Statute. We will be subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts.

These provisions might also have the effect of preventing changes in our management. It is also possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Choice of Forum. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty; (iii) any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate or our amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and (v) any action asserting a claim against us that is governed by the internal-affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is 718-921-8300. Our shares of common stock will be issued in uncertificated form only, subject to limited circumstances.

Market Listing

We have applied to list our common stock on the NYSE under the symbol "RMED."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to the completion of this offering, there has been no public market for our common stock, and we cannot assure you that a liquid trading market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of shares of common stock, including shares issued upon the exercise of outstanding options and upon the vesting of outstanding restricted stock units, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital in the future. The effect of sales of our common stock in the public market may be exacerbated by the relatively small public float of our common stock following this offering. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of the date of this prospectus, and assuming the sale of all shares offered, upon completion of this offering, shares of common stock will be outstanding. All of the securities sold by in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, unless held by our "affiliates," as that term is defined under Rule 144 under the Securities Act.

The remaining shares of common stock outstanding upon the closing of this offering will be "restricted securities," as defined under Rule 144 of the Securities Act. Restricted securities may be sold in the U.S. public market only if registered or if they qualify for an exemption from registration, including by reason of Rule 144 or 701 under the Securities Act, which rules are summarized below. All of our executive officers, directors and holders of substantially all of our capital stock and equity award recipients have entered into market standoff agreements with us or into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus. Subject to the lock-up agreements described below, the applicable conditions of Rule 144 or Rule 701 and our insider trading policy, these restricted securities will generally become available for sale in the public market as follows:

- beginning on the date of this prospectus, all shares of our common stock sold in this offering will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, the remainder of the shares of our common stock will be eligible for sale in the public market from time to time thereafter, subject in some cases to the volume and other restrictions of Rule 144, our insider trading policy, and certain of our market standoff agreements, as described below.

Lock-Up Agreements

We, our officers and directors and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock, will agree that, subject to certain exceptions and under certain conditions, for a period of 180 days after the date of this prospectus, we and they will not, without the prior written consent of Piper Jaffray & Co. and Cantor Fitzgerald & Co., dispose of or hedge any shares or any securities convertible into or exchangeable for shares of our capital stock. These agreements are described in the section captioned "Underwriters" located elsewhere in this prospectus.

Rule 144

In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock to be sold

for at least six months, would be entitled to sell an unlimited number of shares of our common stock, provided current public information about us is available. In addition, under Rule 144, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares of our common stock to be sold for at least one year, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months are entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; and
- the average weekly trading volume of our common stock on during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale, or if no such notice is required, the date of receipt of the order to execute the sale.

Sales of restricted shares under Rule 144 by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares are required to wait until ninety (90) days after the date of this prospectus before selling their shares under Rule 701.

Registration Statement on Form S-8

As of July 13, 2018 options to purchase an aggregate of 1,892,000 shares of our common stock were outstanding, and restricted stock units covering 1,337,722 shares of our common stock were outstanding. Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register shares of our common stock issued or reserved for issuance under our equity compensation plans. The registration statement on Form S-8 will become effective immediately upon filing, and shares covered by such registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. See the section captioned “Executive compensation—Employee benefit and stock plans” for additional information.

Registration Rights

We have not granted any registration rights.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF THE OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK

The following is a general discussion of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) with respect to their ownership and disposition of our common stock purchased in this offering. This discussion is for general information only, is not tax advice and does not purport to be a complete analysis of all the potential tax considerations. This discussion is based upon the provisions of the United States Internal Revenue Code of 1986, as amended, or the Code, existing and proposed Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all in effect as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This discussion does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal gift and estate tax laws. In addition, this discussion does not address any tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- persons subject to the alternative minimum tax or the Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons whose functional currency is not the U.S. dollar;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any warrant or option or otherwise as compensation;
- persons who hold or receive our common stock pursuant to conversion rights under convertible instruments;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code; or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership, entity or arrangement classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, entities classified as partnerships for U.S. federal income tax purposes and other pass-through entities that hold our common stock, as well as partners or members in such entities, should consult their tax advisors.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax laws or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty. In addition, significant changes in U.S. federal income tax laws were recently enacted. You should consult with your tax advisor with respect to such changes in U.S. tax law as well as potentially conforming changes in state tax laws.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder if you are any holder of our common stock other than a partnership (or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) or:

- an individual who is a citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust if it (x) is subject to the primary supervision of a U.S. court and one or more U.S. persons have the authority to control all substantial decisions of the trust or (y) has made a valid election under applicable Treasury Regulations to be treated as a U.S. person.

Distributions

As described in the section captioned “Dividend policy,” we have never declared or paid cash dividends on our capital stock and do not anticipate paying any dividends on our capital stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under “Gain on Disposition of Our Common Stock.”

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the United States) are generally exempt from the withholding tax described in the previous paragraph, subject to the discussion below on backup withholding. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits,

subject to an applicable income tax treaty providing otherwise. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

If you hold our common stock through a financial institution or other agent acting on your behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. You may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Disposition of Common Stock

Subject to the discussion below on backup withholding and on common stock held by or through foreign entities, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the United States);
- you are a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, your common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 24% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed and appropriate IRS Form W-8 or otherwise meets documentary evidence requirements for establishing non- U.S. holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the U.S. through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, you may be able to obtain a refund or credit from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act and the rules and regulations promulgated thereunder, collectively FATCA, generally impose withholding tax at a rate of 30% on dividends on, and gross proceeds from the sale or other disposition of, our common stock paid to a “foreign financial institution” (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a “non-financial foreign entity” (as specially defined under these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. You should consult your tax advisors regarding the possible implications of FACTA on your investment in our common stock.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

We are offering the shares of our common stock described in this prospectus through the underwriters named below. Piper Jaffray & Co. and Cantor Fitzgerald & Co. are acting as joint book-running managers of this offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase, and we have agreed to sell to the underwriters, the number of shares of common stock listed next to its name in the following table.

Underwriters	Number of Shares
Piper Jaffray & Co.	
Cantor Fitzgerald & Co.	
SunTrust Robinson Humphrey, Inc.	
Nomura Securities International, Inc.	
Total	

The underwriting agreement provides that the underwriters must buy all of the shares of common stock if they buy any of them. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares as described below.

Our common stock is offered subject to a number of conditions, including:

- receipt and acceptance of our common stock by the underwriters; and
- the underwriters' right to reject orders in whole or in part.

We have been advised by the representatives that the underwriters intend to make a market in our common stock but that they are not obligated to do so and may discontinue making a market at any time without notice.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically.

Option to Purchase Additional Shares

We have granted the underwriters an option to buy up to an aggregate of additional shares of our common stock. The underwriters have 30 days from the date of this prospectus to exercise this option. If the underwriters exercise this option, they will each purchase additional shares of common stock approximately in proportion to the amounts specified in the table above.

Underwriting Discount

Shares sold by the underwriters to the public will initially be offered at the initial offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. The underwriters may offer the shares through one or more of their affiliates or selling agents. If all the shares are not sold at the initial public offering price, the representatives may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares at the prices and upon the terms stated therein.

The following table shows the per share and total underwriting discount we will pay to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase up to additional shares.

	No Exercise	Full Exercise
Per share	$	$
Total	$	$

We estimate that the total expenses of the offering payable by us, not including the underwriting discount, will be approximately $ million.

No Sales of Similar Securities

We, our executive officers and directors, and holders of all of our common stock have entered into lock-up agreements with the underwriters. Under the lock-up agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of Piper Jaffray & Co. and Cantor Fitzgerald & Co., offer, sell, contract to sell, pledge, or otherwise dispose of, directly or indirectly, or hedge our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus.

Piper Jaffray & Co. and Cantor Fitzgerald & Co. may, at any time and in their sole discretion, release some or all the securities from these lock-up agreements. If the restrictions under the lock-up agreements are waived, shares of our common stock may become available for resale into the market, subject to applicable law, which could reduce the market price of our common stock.

Indemnification

We have agreed to indemnify the several underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters may be required to make in respect of those liabilities.

New York Stock Exchange

We have applied to have our common stock approved for listing on the NYSE under the symbol "RMED."

Price Stabilization, Short Positions

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed

a specified maximum. These transactions may also include making short sales of our common stock, which involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering and purchasing shares of common stock on the open market to cover short positions created by short sales. Short sales may be "covered short sales," which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked short sales," which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on the NYSE, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. Neither we, nor any of the underwriters make any representation that the underwriters will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

Determination of Offering Price

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation among us and the representatives of the underwriters. The principal factors to be considered in determining the initial public offering price include:

- the information set forth in this prospectus and otherwise available to the representatives;
- our history and prospects and the history and prospects for the industry in which we compete;
- our past and present financial performance;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities market at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

The estimated public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock or that the common stock will trade in the public market at or above the initial public offering price.

Affiliations

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and their affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of us. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Notice to Prospective Investors in Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI

33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "**Relevant Member State**") an offer to the public of any shares which are the subject of the offering contemplated by this prospectus (the "**Shares**") may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Directive;

(b) by the Managers to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of Lead Manager for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of Shares shall result in a requirement for the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "**offer to the public**" in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. The expression "**Prospectus Directive**" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression "**2010 PD Amending Directive**" means Directive 2010/73/EU.

The EEA selling restriction is in addition to any other selling restrictions set out in this prospectus.

Notice to Prospective Investors in Australia

This prospectus is not a formal disclosure document and has not been, nor will be, lodged with the Australian Securities and Investments Commission. It does not purport to contain all information that an investor or their professional advisers would expect to find in a prospectus or other disclosure document (as defined in the Corporations Act 2001 (Australia)) for the purposes of Part 6D.2 of the Corporations Act 2001 (Australia) or in a product disclosure statement for the purposes of Part 7.9 of the Corporations Act 2001 (Australia), in either case, in relation to the securities.

The securities are not being offered in Australia to "retail clients" as defined in sections 761G and 761GA of the Corporations Act 2001 (Australia). This offering is being made in Australia solely to "wholesale clients" for the purposes of section 761G of the Corporations Act 2001 (Australia) and, as such, no prospectus, product disclosure statement or other disclosure document in relation to the securities has been, or will be, prepared.

This prospectus does not constitute an offer in Australia other than to persons who do not require disclosure under Part 6D.2 of the Corporations Act 2001 (Australia) and who are wholesale clients for the purposes of section 761G of the Corporations Act 2001 (Australia). By submitting an application for our securities, you represent and warrant to us that you are a person who does not require disclosure

under Part 6D.2 and who is a wholesale client for the purposes of section 761G of the Corporations Act 2001 (Australia). If any recipient of this prospectus is not a wholesale client, no offer of, or invitation to apply for, our securities shall be deemed to be made to such recipient and no applications for our securities will be accepted from such recipient. Any offer to a recipient in Australia, and any agreement arising from acceptance of such offer, is personal and may only be accepted by the recipient. In addition, by applying for our securities you undertake to us that, for a period of 12 months from the date of issue of the securities, you will not transfer any interest in the securities to any person in Australia other than to a person who does not require disclosure under Part 6D.2 and who is a wholesale client.

Notice to Prospective Investors in Hong Kong

The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our securities may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to "professional investors" within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the SFO and any rules made thereunder.

Notice to Prospective Investors in Japan

Our securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and our securities will not be offered or sold, directly or indirectly, in Japan, or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan, or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This document has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this document and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of our securities may not be circulated or distributed, nor may our securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "**SFA**"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where our securities are subscribed or purchased under Section 275 by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired our securities pursuant to an offer made under Section 275 except:

(1) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(2) where no consideration is or will be given for the transfer;

(3) where the transfer is by operation of law; or

(4) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Switzerland

The Prospectus does not constitute an issue prospectus pursuant to Article 652a or Article 1156 of the Swiss Code of Obligations ("CO") and the shares will not be listed on the SIX Swiss Exchange. Therefore, the Prospectus may not comply with the disclosure standards of the CO and/or the listing rules (including any prospectus schemes) of the SIX Swiss Exchange. Accordingly, the shares may not be offered to the public in or from Switzerland, but only to a selected and limited circle of investors, which do not subscribe to the shares with a view to distribution.

Notice to Prospective Investors in United Kingdom

This prospectus is only being distributed to and is only directed at: (1) persons who are outside the United Kingdom; (2) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (3) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons falling within (1)-(3) together being referred to as "relevant persons"). The shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Diego, California. The underwriters are being represented by Cooley LLP, New York, New York, in connection with this offering.

EXPERTS

The financial statements as of and for the years ended December 31, 2016 and 2017 included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to the restatement of the 2016 financial statements). Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at www.ramed.com. Upon completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

INDEX TO FINANCIAL STATEMENTS

RA MEDICAL SYSTEMS, INC.

Report of Independent Registered Public Accounting Firm

To the stockholders and the Board of Directors of
Ra Medical Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ra Medical Systems, Inc. (the "Company") as of December 31, 2016 and 2017, the related statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes to the financial statements (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2016 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Restatement of the 2016 Financial Statements

As discussed in Note 3 to the financial statements, the accompanying 2016 financial statements have been restated.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
May 18, 2018

We have served as the Company's auditor since 2018.

Ra Medical Systems, Inc.

Balance Sheets
(in thousands, except share and per share data)

	December 31, 2016 (restated)	2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,921	$ 8,237
Accounts receivable, net	393	517
Inventories, net	870	1,196
Prepaid expenses and other current assets	124	92
Total current assets	5,308	10,042
Property and equipment, net	506	1,159
Other non-current assets	28	68
TOTAL ASSETS	$ 5,842	$ 11,269
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 473	$ 426
Accrued expenses	419	324
Current portion of deferred revenue	1,744	1,714
Current portion of equipment financing	42	44
Other current liabilities	32	125
Total current liabilities	2,710	2,633
Deferred revenue	836	775
Equipment financing	65	19
Stock-based compensation liability	2,611	15,376
Other liabilities	—	81
Total liabilities	6,222	18,884
Commitments and contingencies (Note 13)		
Stockholders' Deficit		
Common stock, no par value, 10,000,000 shares authorized; 7,462,720 and 7,888,170 issued and outstanding, respectively	—	—
Additional paid-in capital	11,244	21,774
Accumulated deficit	(11,624)	(29,389)
Total stockholders' deficit	(380)	(7,615)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 5,842	$ 11,269

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Operations
(in thousands, except per share data)

	Year ended December 31,	
	2016 (restated)	2017
Net revenue		
Product sales	$ 3,817	$ 3,067
Service and other	2,159	2,803
Total net revenue	5,976	5,870
Cost of revenue		
Product sales	2,289	2,854
Service and other	849	1,311
Total cost of revenue	3,138	4,165
Gross profit	2,838	1,705
Operating expenses		
Selling, general and administrative	5,321	14,947
Research and development	1,715	4,518
Total operating expenses	7,036	19,465
Operating loss	(4,198)	(17,760)
Other expense		
Interest expense	3	4
Total other expense	3	4
Loss before income tax expense	(4,201)	(17,764)
Income tax expense	1	1
Net loss	(4,202)	(17,765)
Basic and diluted net loss per share	$ (0.60)	$ (2.35)
Basic and diluted weighted average common shares outstanding	6,951	7,545

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Stockholders' Deficit
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Deficit
Balances at December 31, 2015 (as previously reported)	6,739	$ 68	$ 5,828	$ (7,042)	$ (1,146)
Prior period error (Note 3)	49	(68)	68	(380)	(380)
Balances at December 31, 2015 (restated)	6,788	—	5,896	(7,422)	(1,526)
Common stock issued (restated)	658	—	5,265	—	5,265
Common stock issued for services	17	—	83	—	83
Net loss (restated)	—	—	—	(4,202)	(4,202)
Balances at December 31, 2016 (restated)	7,463	—	11,244	(11,624)	(380)
Common stock issued	421	—	10,430	—	10,430
Common stock issued for services	4	—	100	—	100
Net loss	—	—	—	(17,765)	(17,765)
Balances at December 31, 2017	7,888	$ —	$ 21,774	$ (29,389)	$ (7,615)

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Cash Flows
(in thousands)

	Year ended December 31,	
	2016 (restated)	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,202)	$(17,765)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	95	218
Provision for doubtful accounts	12	—
Stock-based compensation	2,300	12,706
Common stock issued in exchange for services	42	100
Loss on disposal of property and equipment	—	53
Changes in operating assets and liabilities:		
Accounts receivable	(161)	(124)
Inventories	(181)	(644)
Prepaid expenses and other assets	(34)	(8)
Accounts payable	124	(47)
Accrued expenses	(103)	(95)
Deferred revenue	360	(91)
Other liabilities	(138)	174
Net cash used in operating activities	(1,886)	(5,523)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(210)	(547)
Net cash used in investing activities	(210)	(547)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	5,265	10,430
Proceeds from equipment financing	130	—
Payments on equipment financing	(22)	(44)
Net cash provided by financing activities	5,373	10,386
NET CHANGE IN CASH AND CASH EQUIVALENTS	3,277	4,316
CASH AND CASH EQUIVALENTS, beginning of year	644	3,921
CASH AND CASH EQUIVALENTS, end of year	$ 3,921	$ 8,237
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:		
Stock issued for software implementation services	$ 42	$ —
Transfer from inventories to property and equipment for demonstration lasers and lasers placed with customers	$ 93	$ 377
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 3	$ 4
Cash payments for taxes	$ 1	$ 1

See notes to financial statements.

Ra Medical Systems, Inc.

Notes to Financial Statements

Note 1—Organization and Nature of Operations

Ra Medical Systems, Inc. (the "Company") was formed in September 4, 2002, in the state of California. The Company is a medical device company commercializing advanced excimer lasers for use in the treatment of dermatologic and vascular diseases. The Company develops, manufactures and markets medical devices targeting the dermatology and vascular specialties. The Company's product development centers around proprietary applications of its excimer technology for use in the treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma and peripheral artery disease ("PAD").

Note 2—Significant Accounting Policies

Use of estimates—The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and reported disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. The Company's financial statements are based upon a number of estimates, including but not limited to, accounts receivable reserves, inventory reserves, reserves for warranty costs, fair value of stock option awards granted and revenue recognition for multiple element arrangements.

Cash and cash equivalents—The Company considers all short-term, highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents primarily represent funds invested in readily available checking and money market accounts.

Accounts receivable, net—Trade accounts receivable are presented net of allowances for doubtful accounts and other credits.

The Company sells or leases its lasers to distributors or physicians directly with various forms of financing options. The Company does business and extends credit based on an evaluation of the customers' financial condition generally without requiring collateral. Exposure to losses on trade receivables is expected to vary by customer due to the financial condition of each customer. The Company monitors exposure to credit losses and maintains allowances for anticipated losses considered necessary under the circumstances.

The Company maintains an allowance for doubtful accounts for balances that appear to have specific collection issues. The collection process is based on the age of the invoice and requires attempted contacts with the customer at specified intervals. If, after a specified number of days, the Company has been unsuccessful in its collection efforts, provision for doubtful accounts is recorded for the balance in question. Delinquent accounts receivable are charged against the allowance for doubtful accounts once the Company has determined the amounts are uncollectible. The factors considered in reaching this determination are the apparent financial condition of the customer and the Company's success in contacting and negotiating with the customer. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

The following table shows the allowance for doubtful accounts activity (in thousands):

	December 31,	
	2016	2017
Balanced at beginning of period	$—	$ 12
Provision for doubtful accounts	12	—
Write-offs	—	—
Balance at end of period	$ 12	$ 12

Inventories, net—Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Cost includes materials, labor and manufacturing overhead related to the purchase and production of inventories. The Company reduces the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technological developments or other economic factors.

Property and equipment, net—Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives as follows:

Computer hardware and software	4 years
Furniture and fixtures	5 years
Machinery and equipment	10 years
Demonstration lasers and lasers placed with customers	5 years
Automobiles	5 years

Leasehold improvements are depreciated over the shorter of the useful life of the leasehold improvement or the term of the underlying property's lease.

When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the account balances and any resulting gain or loss is recognized in income for the period. The cost of repairs and maintenance is expensed as incurred, whereas significant betterments are capitalized.

Impairment of long-lived assets—The Company periodically reviews its long-lived assets for impairment when certain events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. Should the sum of the undiscounted expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. There were no impairment charges for the years ended December 31, 2016 or 2017.

Fair value of financial instruments—Cash and cash equivalents, trade accounts receivable, accounts payable, accrued expenses, deferred revenue and other current assets and liabilities are reported on the balance sheet at carrying value which approximates fair value due to the short-term maturities of these instruments.

The fair value of the Company's debt, which is classified as equipment financing liability on the balance sheets, is estimated based on current rates offered to the Company for similar debt and approximates carrying value.

Fair value measurements—Fair value represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants and is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier value hierarchy is used to identify inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Inputs other than the quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and

Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The Company's only assets or liabilities measured at fair value are its stock-based compensation liability and its abandoned operating lease. Note 11 and Note 13 discuss the valuation techniques for the stock-based compensation liability and abandoned operating lease, respectively.

Product warranty—The Company records estimated product warranty costs at the time of sale. Products are warrantied against defects in material and workmanship when properly used for their intended purpose and appropriately maintained. Product warranties are included for the first year after the sale. The product warranty liability is determined based on historical information such as past experience, product failure rates or number of units repaired, estimated cost of material and labor, and in certain instances, estimated property damage. The customer may purchase an extended service contract, which is either negotiated in the contract or sold as a separate component for which revenue is deferred over the term of the agreement.

The warranty accrual is included in accrued expenses in the accompanying balance sheets. Warranty expenses are included in cost of sales in the accompanying statements of operations. Changes in estimates to previously established warranty accruals result from current period updates to assumptions regarding repair costs and are included in current period warranty expense.

Revenue recognition

Product Sales

The Company recognizes revenues from the product sales when the following four criteria have been met: (i) the product has been shipped or services have been performed and the Company has no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of provisions for estimated expected returns and cash discounts.

None of the Company's sales contain right-of-return provisions and the Company has historically only experienced nominal returns. However, the Company estimates a provision for expected returns for the

catheter sales used in its DABRA laser system. The provision is based on the Company's best estimate of the number of products that will be returned as defective products based on the nature of the consumable. No provision is made for expected returns from other product sales, including the sales of devices, as the Company does not have a history of returns. If it becomes known that actual return rates deviate from the Company's original estimates, the provision for expected returns will be adjusted accordingly. The provision for expected returns is recorded as a reduction of accounts receivable and product sales.

The Company also offers certain cash discounts associated with the sales of its products. These discounts are negotiated on a transaction by transaction basis and therefore do not include any estimate at the time of sale. The discounts are recorded as a reduction to accounts receivable and product sales.

For shipment of its products, the Company takes into account the time at which to recognize revenue, generally this is when title and risk of loss is transferred.

Multiple Element Arrangements

The Company regularly enters into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include an instrument and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

Arrangement consideration is then allocated to those separate units of account based on their relative selling price. When applying the relative selling price method, the selling price for each deliverable is determined using the following hierarchy: (i) vendor-specific objective evidence ("VSOE") of the selling price; (ii) third-party evidence of selling price; or (iii) best estimated selling price. The Company records revenue related to these multiple deliverables as products are delivered and services are performed. In order to establish VSOE of selling price, the Company must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. In cases where there is not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then the Company utilizes third-party evidence of selling price, if available, or best estimated selling price ("BESP").

The Company determines BESP for an individual element based on the average selling price of such discrete element during the annual period, excluding transactions that are not representative of standalone sales. The Company regularly reviews and maintains its BESP and updates these estimates at least annually.

Billable Service Arrangements

Revenue from billable services, including repair activity, is recognized when the service is provided.

Extended Warranty Arrangements

Revenues received with respect to extended warranties on products are recognized over the duration of the extended warranty period on a straight-line basis.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Lease Arrangements

The Company also derives revenue pursuant to product lease agreements. These leases are classified as operating leases in accordance with the relevant accounting guidelines, and the related revenue is recognized on a straight-line basis.

Distributor Transactions

In certain markets, the Company sells products and provides services to customers through distributors that specialize in medical device products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. These transactions are accounted for in accordance with the Company's revenue recognition policy described herein.

Shipping and handling costs—Shipping and handling charged to customers is included in net product sales. Shipping and handling costs are included in selling, general and administrative expenses in the accompanying statements of operations. Shipping and handling costs were $0.2 million and $0.3 million for the years ended December 31, 2016 and 2017, respectively.

Advertising expense—The Company charges advertising costs to expense as incurred. Advertising expense for the years ended December 31, 2016 and 2017, amounted to $7,500 and $23,000, respectively.

Research and development—Major components of research and development costs include personnel compensation expenses, stock-based compensation, consulting, materials and clinical trial expenses. Research and development expenses are charged to operations in the period they are incurred.

Patents—The Company expenses patent costs, including related legal costs, as incurred and records such costs within selling, general and administrative expense in the accompanying statements of operations.

Stock-based compensation—The Company evaluates whether an award should be classified and accounted for as a liability award or equity award for all stock-based compensation awards granted.

Stock-based compensation for liability awards issued to employees, directors, consultants, and other service providers is measured based on fair value of the award using the Black Scholes option pricing model. Changes in the fair value of a liability incurred under a share-based payment arrangement that occur during the requisite service period are recognized as compensation cost over that period. The percentage of the fair value that is accrued as compensation cost at the end of each period is equal to the percentage of the requisite service that has been rendered at that date. Any difference between the amount for which a liability award is settled and its fair value at the settlement date is recorded as an adjustment to compensation cost in the period of settlement.

Stock-based compensation expense for equity instruments issued to employees and directors is measured based on estimating the fair value of each stock option on the date of grant using the Black Scholes option pricing model. Equity instruments issued to nonemployee consultants and service providers are valued using the Black Scholes option pricing model and are subject to revaluation as the underlying equity instruments vest.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

As of December 31, 2016 and 2017, all stock-based compensation awards have been classified as liabilities in the financial statements. See Note 11.

The Company recognizes stock-based compensation expense as follows:

	Employees	Nonemployees
Service condition only	Straight-line	Re-value through the performance commitment date
Performance criterion is probable of being met:		
Service criterion is complete	Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence	Re-value the award once the performance criterion is considered probable of occurrence and recognize expense for the then fair value of the award
Service criterion is not complete	Straight-line	Straight-line, except the award is re-valued through the performance commitment date
Performance criterion is not probable of being met	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above

Income taxes—The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences reverse. Any resulting net deferred tax assets are evaluated for recoverability and, accordingly, a valuation allowance is provided when it is more likely than not that all or some portion of the deferred tax asset will not be realized.

The Company accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining whether it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. An uncertain tax position is considered effectively settled on completion of an examination by a taxing authority if certain other conditions are satisfied. Should the Company incur interest and penalties relating to tax uncertainties, such amounts would be classified as a component of interest expense and other expense, respectively.

Comprehensive loss—Comprehensive loss is equal to net loss for all periods presented.

Concentrations of credit risk—Credit risk represents the accounting loss that would be recognized at the reporting date if counterparties failed completely to perform as contracted. Concentrations of credit risk that arise from financial instruments exist for groups of customers or counterparties when they have similar economic characteristics that would cause their ability to meet contractual obligations to be similarly affected by changes in economic or other conditions described below.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Financial instruments, which potentially subject the Company to concentration of credit risk, consist of cash balances maintained in excess of Federal Depository Insurance Corporation limits, and accounts receivable which have no collateral or security. The Company monitors the financial condition of the banks in which it currently has deposits. The Company has not experienced any significant losses in this respect and believes that it is not exposed to any significant related risk.

Exposure to losses on accounts receivable is dependent on the individual customer's financial condition. The Company monitors its exposure to credit losses and reserves for those accounts receivable that it deems to be not collectible.

As of December 31, 2016, accounts receivable due from two of the Company's customers was 37%, and as of December 31, 2017, accounts receivable due from four of the Company's customers was 57% of accounts receivable.

No individual customer represented greater than 10% of total net revenue for the years ended December 31, 2016 or 2017.

Recent accounting pronouncements—On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the "JOBS Act") into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies, which are the dates included below.

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. The Company adopted ASU 2014-15 effective January 1, 2017. The impact on the financial statements and related disclosures was not material.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, ("ASU 2015-11"). The update requires that for entities that measure inventory using the first-in, first-out method, inventory should be measured at the lower of cost and net realizable value. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The update is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company early adopted ASU 2015-11 effective January 1, 2017. The impact on the financial statements and related disclosures was not material.

In March 2016, FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*. The ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2017, with early adoption permitted. The Company early adopted ASU 2016-09 effective January 1, 2017. The impact on these financial statements and related disclosures was not material.

In May 2014, FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and issued subsequent amendments to the initial guidance in August 2015, March 2016, April 2016 and May 2016 within ASU 2015-14, ASU 2016-08, ASU 2016-10 and ASU 2016-12, respectively. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles in the United States ("US GAAP"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle, and in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing US GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation, among others. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2018 with (i) retrospective application of ASU 2014-09 to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09 or (ii) retrospective application of ASU 2014-09 with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. The Company does not believe adoption of this guidance will have a material impact on revenue recognition, but it will require additional disclosures.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). This update requires lessees to recognize on the balance sheet a lease liability and a lease asset for all leases with a term greater than 12 months, including operating leases. The update also expands the required quantitative and qualitative disclosures surrounding leases. Under the new standard, the Company will have to recognize a liability representing its lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet. ASU 2016-02 is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is evaluating the effect that this guidance will have on the financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. Under the ASU, an entity will account for the effects of a modification unless (i) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified, (ii) the vesting conditions of the modified award are the same vesting conditions as the original award immediately before the original award is modified and (iii) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments in this ASU are effective prospectively for fiscal years, and interim periods within those annual periods, beginning after December 15, 2017. This adoption of this ASU is not expected to have a material impact on the Company's financial statements or related disclosures.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Note 3—Restatement and reclassifications

Subsequent to the issuance of the Company's financial statements as of and for the year ended December 31, 2016, which statements have been reaudited, management identified certain errors consisting of:

- The Company determined that stock option awards that were communicated to employees, directors, consultants and service providers (together the "Optionees") were not validly authorized. Although the communicated awards are not outstanding options, the Company believes the communicated awards represent a contractual obligation to the Optionees. As a result, the awards are required to be classified as liabilities remeasured at each reporting date, rather than as equity-classified option awards as previously reported. This resulted in an understatement of the total stock-based compensation expense of $2.0 million in 2016, the reversal of stock-based compensation expense previously recorded to additional paid-in capital of $0.3 million, and a cumulative adjustment to beginning accumulated deficit of $0.3 million.
- Deferred rental income of $0.1 million as of December 31, 2016, previously included as a component of accrued expenses rather than as a component of deferred revenue, current portion.
- A misstatement of $0.1 million of the total amount of depreciation and amortization expense included on the statement of cash flows in 2016. The amounts presented for total cash used operating activities on the statement of operations were correct.
- Other miscellaneous items related to accounts receivable, deferred revenue, accrued expenses, common stock, product sales and cost of sales.
- There were corresponding misstatements in the statement of cash flows for the above matters.

As a result of these errors, the Company has restated the accompanying 2016 financial statements.

The Company also made certain reclassifications of amounts previously presented to conform to the current period. Such reclassifications on the balance sheet include $0.1 million of demonstration laser devices previously included in inventory to property and equipment, net. Such reclassifications on the statement of operations include changes in presentation of net revenues to separately present product sales and service and other revenues separately to conform to the United States Securities and Exchange Commission requirements. There were other miscellaneous reclassifications made between line items for customer deposits, shipping and handling amounts charged to customers and interest expense on corporate credit card balances. There were corresponding impacts to the statement of cash flows.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

The following is a summary of the impact of the restatement and reclassifications on the Company's balance sheet, (in thousands):

	December 31, 2016			
	As Previously Reported	Correction of Errors	Reclassifications	As Restated
Accounts receivable, net	$ 405	$ (12)	$ —	$ 393
Inventories, net	964	(1)	(93)	870
Total current assets	5,414	(13)	(93)	5,308
Property and equipment, net	413	—	93	506
Total assets	5,855	(13)	—	5,842
Accrued expenses	591	(162)	(10)	419
Current portion of deferred revenue	1,620	124	—	1,744
Other current liabilities	22	—	10	32
Total current liabilities	2,748	(38)	—	2,710
Deferred revenue	804	32	—	836
Stock-compensation liability	—	2,611	—	2,611
Total liabilities	3,617	2,605	—	6,222
Common stock	75	(75)	—	—
Additional paid-in capital	11,496	(252)	—	11,244
Accumulated deficit	(9,333)	(2,291)	—	(11,624)
Total stockholders' equity (deficit)	2,238	(2,618)	—	(380)
Total liabilities and stockholders' equity (deficit)	$ 5,855	$ (13)	$ —	$ 5,842

The following is a summary of the impact of the restatement and reclassifications on the Company's statement of operations, (in thousands):

	Year ended December 31, 2016			
	As Previously Reported	Correction of Errors	Reclassifications	As Restated
Product sales	$ —	$ (5)	$ 3,822	$ 3,817
Service and other	—	—	2,159	2,159
Total net revenue	5,937	(5)	44	5,976
Product	—	87	2,202	2,289
Service and other	—	(19)	868	849
Total cost of sales	3,070	68	—	3,138
Gross profit	2,867	(73)	44	2,838
Selling, general and administrative	4,335	924	62	5,321
Research and development	801	914	—	1,715
Total operating expenses	5,136	1,838	62	7,036
Operating loss	(2,269)	(1,911)	(18)	(4,198)
Interest expense	21	—	(18)	3
Loss before income tax	(2,290)	(1,911)	—	(4,201)
Net loss	$ (2,291)	$ (1,911)	$ —	$ (4,202)

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

The following is a summary of the impact of the restatement and reclassifications on the Company's statement of cash flows, (in thousands):

	Year ended December 31, 2016			
	As Previously Reported	Correction of Errors	Reclassifications	As Restated
Net loss	$ (2,291)	$ (1,911)	$ —	$ (4,202)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	5	90	—	95
Provision for doubtful accounts	—	12	—	12
Stock-based compensation	325	1,975	—	2,300
Changes in operating assets and liabilities:				
Inventories	(156)	(25)	—	(181)
Accrued expenses	(62)	(165)	124	(103)
Deferred revenue	246	114	—	360
Other liabilities	(14)	—	(124)	(138)
Supplemental disclosure of non-cash investing activities:				
Transfer from inventories to property and equipment for demonstration lasers and lasers placed with customers	—	—	93	93
Supplemental cash flow information:				
Interest	$ 21	$ —	$ (18)	$ 3

The restatement had no net effect on cash flows from operations, investing or financing. The restatement also had a beginning adjustment to accumulated deficit of $0.4 million, of which $0.3 million and $0.1 million related to stock compensation and the other insignificant errors described above, respectively.

Note 4—Inventories, net

Inventories consisted of the following (in thousands):

	December 31	
	2016	2017
Raw materials	$449	$ 705
Work in process	18	110
Finished goods	403	381
Inventories, net	$870	$1,196

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Note 5—Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	December 31, 2016	December 31, 2017
Computer hardware and software	$ 122	$ 301
Furniture and fixtures	41	60
Machinery and equipment	606	745
Demonstration lasers and lasers placed with customers	106	483
Automobiles	85	154
Leasehold improvements	28	13
Construction in progress	107	178
	1,095	1,934
Accumulated depreciation	(589)	(775)
Property and equipment, net	$ 506	$1,159

Depreciation expense was $0.1 million and $0.2 million for the years ended December 31, 2016 and 2017, respectively.

Note 6—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2016	December 31, 2017
Compensation and related benefits	$154	$ 236
Accrued warranty (Note 7)	97	87
Other accrued expenses	168	1
Accrued expenses	$419	$ 324

Note 7—Accrued Warranty

Activity in the product warranty accrual is included in accrued expenses above and consists of the following (in thousands):

	December 31, 2016	December 31, 2017
Balanced at beginning of period	$ 112	$ 97
Increase in warranty accrual	207	198
Claims satisfied	(222)	(208)
Accrued warranty	$ 97	$ 87

Warranty expense was $0.2 million for each of the years ended December 31, 2016 and 2017, respectively, and is included in service and other cost of revenue in the accompanying statements of operations.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Note 8—Long-Term Debt and Equipment Financing

The Company had a line of credit with a bank allowing for borrowing up to $0.3 million, collateralized by personal property of the Company and guaranteed by a shareholder of the Company, with interest at 4.5% per year. There were no balances outstanding on the Company's line of credit as of December 31, 2016. The line of credit expired on September 1, 2017.

During 2016, the Company entered into two loan agreements to finance equipment placed in physician's offices under monthly rental contracts. Interest expense for the years ended December 31, 2016 and 2017 associated with these transactions was $3,000 and $4,000, respectively.

Future maturities are as follows (in thousands):

Years ending December 31,	
2018	$44
2019	19
Total	$63

Note 9—Stockholders' Deficit

Common stock—The Company has one class of stock: common shares. The Company issued 658,125 and 421,450 shares of stock in exchange for $5.3 million and $10.4 million that related to the private placements which took place in 2016 and 2017, respectively.

Common stock issued for services—During 2016 and 2017, the Company paid certain accounting and consulting services with Company stock. In 2016, the Company issued 16,649 shares valued at $0.1 million of which $42,000 was capitalized as part of the implementation of the Company's enterprise resource planning system and $42,000 was expensed as accounting services during the year and included as a component of selling, general and administrative on the statement of operations. In 2017, Company issued 4,000 shares as payment for $0.1 million of consulting services performed and included as a component of selling, general and administrative on the statement of operations.

The number of shares issued was based on the fair value of the common stock at the date of the performance of the accounting and consulting services and the associated to amount owed by the Company in exchange for such services. See Note 11 for further discussion on the valuation techniques used for the Company's common stock.

Note 10—Loss per Share

The Company calculates basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per share would reflect the effects of potentially dilutive securities, if any. For the years ended December 31, 2016 and 2017, basic and diluted loss per share were the same.

Note 11—Stock-Based Compensation

In 2003, the Company adopted a stock option plan, which authorized the board of directors to grant stock option awards to eligible Optionees of the Company. In April 2012, such plan expired. In 2014, the Company established the 2014 Stock Option Plan (the "2014 Plan") whereby 1,000,000 shares of

the Company's common stock were reserved for issuance to eligible Optionees. The 2014 Plan provided for the grant of incentive stock options, non-statutory stock options, stock bonuses and rights to acquire restricted stock. Option awards under the 2014 Plan expired up to a maximum of 10 years from the date of the grant. On May 17, 2018, the Company's board of directors terminated the 2014 Plan.

As described in Note 3, the Company has concluded that option awards communicated to Optionees were not validly authorized. Although the communicated awards are not outstanding options, the Company believes the communicated awards represent a contractual obligation to the Optionees, and the Company has classified the option awards as liabilities in the financial statements.

Obligations under the Plans include time and performance-based awards. For time-based awards, vesting generally occurs over the service period of up to four years. Performance based awards vest at the time that the underlying performance conditions are met.

The liabilities for stock-based compensation awards have been classified as a component of noncurrent liabilities on the balance sheet as the Company does not expect that such amounts will be settled through the use of current assets or through the creation of current liabilities.

A summary of the activity and related information of the awards classified as liabilities and communicated during the year ended December 31, 2017, is presented below:

	Awards	Weighted Average Exercise Price	Weighted Average Remaining Life	Aggregate Intrinsic Value
Outstanding at December 31, 2016	654,500	$ 2.22	5.05	$ 3,781
Granted	394,000	7.35	6.02	
Forfeited	(115,000)	6.00	—	
Outstanding at December 31, 2017	933,500	$ 3.92	4.86	$ 19,676
Exercisable at December 31, 2017	641,000	$ 3.13	4.02	$ 14,019
Vested and expected to vest at December 31, 2017	933,500	$ 3.92	4.86	$ 19,676

No awards expired during the year ended December 31, 2017. There were no stock awards exercised in 2016.

Stock-based compensation expense recorded in operating expenses was as follows (in thousands):

	Year ended December 31,	
	2016	2017
Selling, general and administrative	$1,320	$ 8,744
Research and development	914	3,258
Stock-based compensation in operating expenses	$2,234	$ 12,022

Stock-based compensation amounts of $0.1 million and $0.7 million were capitalized to inventory during the years ended December 31, 2016 and 2017, respectively.

These awards are presented as a stock-based compensation liability which is revalued at each reporting period with the change in fair value recorded to compensation expense. As of December 31, 2016 and 2017, the stock-based compensation liability was $2.6 million and $15.4 million, respectively. The fair value of the stock-based compensation liability was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted in the following table:

	Year ended December 31,	
	2016	2017
Risk-free interest rate	1.45%	1.96%
Volatility	45.35%	43.70%
Expected dividend yield	0.00%	0.00%
Expected life	2.9	2.6

The weighted average fair value for awards granted during 2016 and 2017 is $5.97 and $21.52, respectively. The Company's shares are not traded in any public market. The common stock value as of the date of grant was based on the share price of recent equity issuances, if available. If there were no such recent transactions, the Company's share valuation was estimated using both the income and market approaches, which were weighted 50% each. A discount of 35% was then applied for lack of marketability for the Company's common stock. As of December 31, 2016 and 2017, the dates at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with new third party investors who were not previous shareholders of the Company. The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period. During 2016, the Company early adopted ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which among other things, allows the Company to account for forfeitures as they occur.

Note 12—Income Taxes

A reconciliation of the differences between the United States statutory federal income tax rate and the effective tax rate as provided in the statement of operations is as follows:

	Year ended December 31,	
	2016	2017
Tax computed at the federal statutory rate	34.0%	34.0%
State income taxes, net of federal benefits	5.0	5.8
Tax reform—tax rate change	—	(18.6)
Other	4.4	(0.0)
Change in valuation allowance	(34.6)	(21.2)
	(0.0%)	(0.0%)

The federal and state income tax provision is summarized as follows:

	Year ended December 31,	
	2016	2017
Current		
Federal	$ —	$ —
State	1	1
	1	1
Deferred		
Federal	—	—
State	—	—
	—	—
Income tax expense	$ 1	$ 1

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes, and (b) operating losses and tax credit carryforwards.

The tax effects of significant components of the Company's deferred tax assets (liabilities) are as follows:

	December 31,	
	2016	2017
Deferred Tax Assets:		
Net operating loss carryforwards	$ 1,123	$ 1,994
Other accruals	16	79
Reserves	165	142
Deferred revenue	1,028	697
Capitalized research and development	684	618
Stock-based compensation liability	1,040	4,314
	4,056	7,844
Deferred Tax Liabilities:		
Property and equipment	(1)	(5)
Valuation allowance	(4,055)	(7,839)
Total deferred taxes	$ —	$ —

At December 31, 2017, the Company had available federal and state net operating loss carryforwards of approximately $7.2 million and $7.0 million, respectively, which may be used to offset future federal and state taxable earnings. The federal and state net operating losses begin expiring in 2029. Use of these net operating loss carryforwards may be significantly limited under the tax rules regarding the use of losses following an ownership change under Internal Revenue Code ("IRC") Section 382. The Company has not completed an IRC Section 382 analysis regarding the limitation of net operating losses.

ASC 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is

"more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is not currently more likely than not to be realized and, accordingly, has provided a full valuation allowance at December 31, 2016 and 2017.

The difference between the statutory federal income tax rate and the effective income tax rate reported in the statements of operations is primarily due to the Tax Act (as defined below), state income taxes and the change in the valuation allowance.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is no longer subject to U.S. federal, state and local tax authorities for years before 2013. The Company is not currently under examination by any taxing jurisdiction. As of December 31, 2016 and 2017, there is no accrued interest or penalties recorded in the financial statements. However, the net operating loss carryover may be adjusted three years from the date the loss is utilized on an income tax return.

On December 22, 2017, the President of the United States signed into law the Tax Reform Act (the "Tax Act"). The Tax Act significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, eliminating certain deductions, allowing full expensing of capital spending, implementing a territorial tax system, and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. The Company has completed its analysis of the Tax Act. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 34% to a flat 21% rate, effective January 1, 2018. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the Tax Reform Act, the Company revalued its ending net deferred tax assets at December 31, 2017. The impact of this revaluation was offset by a reduction in the valuation allowance, thus having no impact on the income tax expense recognized in the statement of operations for the year ended December 31, 2017

Note 13—Commitments and Contingencies

Capital stock transactions—The Company has determined that there have been defects with respect to certain capital stock transactions, including stock issuances and a reverse stock split, which were not effected in accordance with the requirements of applicable law. The Company could be subject to claims based on the defects. The Company believes any loss as a result of such defects is remote.

Legal—In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

Lease commitments—The Company has various noncancelable operating leases related to office spaces and manufacturing facilities in Carlsbad, California. In 2017, the Company entered into a new operating lease for office space and manufacturing facilities and abandoned its old leases. The Company recorded an expense and a corresponding liability of $0.2 million as a result of the lease abandonment, which represents the fair value of the lease termination costs upon initial measurement. The liability includes the estimated costs, net of estimated subleasing proceeds, the Company expects to incur during the lease term using the credit-adjusted risk-free interest rate. The initial expense is included in selling, general and administrative expenses in the accompanying statement of operations. The initial liability measured at fair value is included in accrued expenses and other liabilities on the accompanying balance sheet as of

December 31, 2017. In periods subsequent to initial measurement, changes to the liability will be measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

Some of these agreements have escalating rent payment provisions. Rent expense under such agreements is recognized on a straight-line basis. Total rent expense for the years ended December 31, 2016 and 2017, was $0.2 million and $0.3 million, respectively.

Future minimum rental payments due are as follows (in thousands):

Years ending December 31,	
2018	$ 517
2019	500
2020	514
2021	529
2022	432
Thereafter	2,363
Total	$ 4,855

Note 14—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the dermatology segment and the vascular segment.

In deciding how to allocate resources and assess performance, the Company's chief operating decision maker regularly evaluates the sales and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to the Company and not specific to a particular segment; therefore, these amounts are not evaluated by the Company's chief operating decision maker on a segmented basis.

The following tables summarize segment performance for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,	
	2016	2017
Vascular	$ —	$ 259
Dermatology	5,976	5,611
Net revenue	$5,976	$5,870
Vascular	$ —	$ 193
Dermatology	3,138	3,972
Cost of revenue	$3,138	$4,165
Vascular	$ —	$ 66
Dermatology	2,838	1,639
Gross profit	$2,838	$1,705

Generally, all assets are common assets, except for demonstration lasers and lasers placed with customers, which are a subset of property and equipment. Demonstration lasers and lasers placed with customers aggregated in the vascular segment was $12,000 and $0.2 million as of December 31, 2016 and 2017, respectively. Demonstration lasers and lasers placed with customers aggregated in the dermatology segment was $0.1 million and $0.3 million as of December 31, 2016 and 2017, respectively.

No sales to an individual customer or country other than the United States accounted for more than 10% of fiscal year 2016 or 2017 net revenue. Net revenue, classified by the major geographic areas in which our customers are located, was as follows:

	Year ended December 31,	
	2016	2017
United States	$5,735	$5,273
All other countries	241	597
Net revenue	$5,976	$5,870

Note 15—Subsequent Events

The Company has evaluated subsequent events through May 18, 2018, the date these financial statements were issued.

Private Placement Financing—From January 2018 through May 2018, the Company issued 316,080 shares of common stock at a per share price of $25 for aggregate proceeds of $7.9 million in connection with a private placement financing.

Ra Medical Systems, Inc

Condensed Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	December 31, 2017	March 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,237	$ 7,083
Accounts receivable, net	517	479
Inventories, net	1,196	914
Prepaid expenses and other current assets	92	217
Total current assets	10,042	8,693
Property and equipment, net	1,159	1,851
Other non-current assets	68	62
TOTAL ASSETS	$ 11,269	$ 10,606
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 426	$ 599
Accrued expenses	324	375
Current portion of deferred revenue	1,714	1,661
Current portion of equipment financing	44	43
Other current liabilities	125	90
Total current liabilities	2,633	2,768
Deferred revenue	775	747
Equipment financing	19	10
Stock-based compensation liability	15,376	15,900
Other liabilities	81	88
Total liabilities	18,884	19,513
Commitments and contingencies (Note 13)		
Stockholders' Deficit		
Common stock, no par value, 10,000,000 shares authorized; 7,888,170 and 7,944,251 issued and outstanding, respectively	—	—
Additional paid-in capital	21,774	23,175
Accumulated deficit	(29,389)	(32,082)
Total stockholders' deficit	(7,615)	(8,907)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 11,269	$ 10,606

See notes to condensed financial statements.

Ra Medical Systems, Inc

Condensed Statements of Operations (Unaudited)
(in thousands, except per share data)

	Three months ended March 31,	
	2017	2018
Net revenue		
Product sales	$ 405	$ 235
Service and other	660	734
Total net revenue	1,065	969
Cost of revenue		
Product sales	321	342
Service and other	281	394
Total cost of revenue	602	736
Gross profit	463	233
Operating expenses		
Selling, general and administrative	1,745	2,639
Research and development	379	286
Total operating expenses	2,124	2,925
Operating loss	(1,661)	(2,692)
Other expense		
Interest expense	1	1
Total other expense	1	1
Loss before income tax expense	(1,662)	(2,693)
Income tax expense	—	—
Net loss	(1,662)	(2,693)
Basic and diluted net loss per share	$ (0.22)	$ (0.34)
Basic and diluted weighted average common shares outstanding	7,463	7,938

See notes to condensed financial statements.

Ra Medical Systems, Inc

Condensed Statement of Stockholders' Deficit (Unaudited)
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Deficit
Balances at December 31, 2017	7,888	$ —	$ 21,774	$ (29,389)	$ (7,615)
Common stock issued	56	—	1,401	—	1,401
Net loss	—	—	—	(2,693)	(2,693)
Balances at March 31, 2018	7,944	$ —	$ 23,175	$ (32,082)	$ (8,907)

See notes to condensed financial statements.

Ra Medical Systems, Inc

Condensed Statements of Cash Flows (Unaudited)
(in thousands)

	Three months ended March 31,	
	2017	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,662)	$ (2,693)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	96
Provision for doubtful accounts	—	88
Stock-based compensation	426	524
Changes in operating assets and liabilities:		
Accounts receivable	98	(50)
Inventories	(80)	(386)
Prepaid expenses and other assets	23	(119)
Accounts payable	(141)	173
Accrued expenses	(118)	51
Deferred revenue	(277)	(81)
Other liabilities	—	(28)
Net cash used in operating activities	(1,699)	(2,425)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(231)	(120)
Net cash used in investing activities	(231)	(120)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	—	1,401
Payments on equipment financing	(11)	(10)
Net cash (used in) provided by financing activities	(11)	1,391
NET CHANGE IN CASH AND CASH EQUIVALENTS	(1,941)	(1,154)
CASH AND CASH EQUIVALENTS, beginning of period	3,921	8,237
CASH AND CASH EQUIVALENTS, end of period	$ 1,980	$ 7,083
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:		
Transfer from inventories to property and equipment for demonstration lasers and lasers placed with customers	$ 54	$ 668
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 1	$ 1

See notes to condensed financial statements.

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)

Note 1—Organization and Nature of Operations

Ra Medical Systems, Inc. (the "Company") was formed in September 4, 2002, in the state of California. The Company is a medical device company commercializing advanced excimer lasers for use in the treatment of dermatologic and vascular diseases. The Company develops, manufactures and markets medical devices targeting the dermatology and vascular specialties. The Company's product development centers around proprietary applications of its excimer technology for use in the treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma and peripheral artery disease ("PAD").

Note 2—Significant Accounting Policies

Interim condensed financial information—The interim condensed financial statements as of March 31, 2018, and for the three months ended March 31, 2017 and 2018, are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's financial position as of March 31, 2018, and its results of operations, cash flows for the three months ended March 31, 2017 and 2018 and changes in stockholders' deficit for the three months ended March 31, 2018. The financial data and other information disclosed in these notes to financial statements related to the three-month periods are also unaudited. The results of operations for the three months ended March 31, 2018, are not necessarily indicative of the results to be expected for the year ending December 31, 2018, or for any other future annual or interim period. The balance sheet as of December 31, 2017, included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company's audited financial statements included elsewhere in this prospectus.

Use of estimates—The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and reported disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. The Company's financial statements are based upon a number of estimates, including but not limited to, accounts receivable reserves, inventory reserves, reserves for warranty costs, fair value of stock option awards granted and revenue recognition for multiple element arrangements.

Recent accounting pronouncements—On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the "JOBS Act") into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies, which are the dates included below.

In May 2014, FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and issued subsequent amendments to the initial guidance in August 2015, March 2016, April 2016 and May 2016 within ASU 2015-14, ASU 2016-08, ASU 2016-10 and ASU 2016-12, respectively. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles in the United States ("US GAAP"). The core principle of

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle, and in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing US GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation, among others. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2018, and interim reporting periods within annual reporting periods beginning after December 15, 2019, with (i) retrospective application of ASU 2014-09 to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09 or (ii) retrospective application of ASU 2014-09 with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09 (the modified retrospective method).

While the Company has not completed its evaluation, the Company currently plans to adopt this accounting standard in the first quarter of fiscal year 2019 using the modified retrospective method. Based on the analysis performed through the first quarter of 2018, the Company does not believe adoption of this guidance will have a material impact on the timing and measurement of revenue under its contracts with customers, but will require additional disclosures.

The new standard also requires an entity to recognize as an asset the incremental costs of obtaining a contract with a customer if the entity expects to recover those costs.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). This update requires lessees to recognize on the balance sheet a lease liability and a lease asset for all leases with a term greater than 12 months, including operating leases. The update also expands the required quantitative and qualitative disclosures surrounding leases. Under the new standard, the Company will have to recognize a liability representing its lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet. ASU 2016-02 is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted.

Lessor accounting under ASU 2016-02 is similar to the current model but updated to align with certain changes to the lessee model. Lessors will continue to classify leases as operating, direct financing or sales-type leases. In addition, the new standard requires that lease and nonlease components of a contract be bifurcated, with nonlease components subject to the new revenue recognition standard effective upon adoption of the new leasing standard. In January 2018, the FASB issued a proposed amendment that, if adopted by the FASB, would allow lessors to elect to account for the lease and nonlease components as a single combined lease component if (i) the timing and pattern of the revenue recognition is the same, and (ii) the combined lease component would continue to be classified as an operating lease.

The Company is evaluating the effect that this guidance will have on the financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. Under the ASU, an entity will account for the effects of a modification unless (i) the fair value of the

modified award is the same as the fair value of the original award immediately before the original award is modified, (ii) the vesting conditions of the modified award are the same vesting conditions as the original award immediately before the original award is modified and (iii) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments in this ASU are effective prospectively for fiscal years, and interim periods within those annual periods, beginning after December 15, 2017. The Company adopted ASU 2017-09 on January 1, 2018, and the adoption did not have a material impact on the Company's financial statements or related financial statement disclosure.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 expands the scope of Topic 718, *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, *Revenue from Contracts with Customers*. The Company is evaluating the effect that this guidance will have on the financial statements and related disclosures.

Note 3—Inventories, net

Inventories consisted of the following (in thousands):

	December 31, 2017	March 31, 2018
Raw materials	$ 705	$ 567
Work in process	110	97
Finished goods	381	250
Inventories, net	$ 1,196	$ 914

Note 4—Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	December 31, 2017	March 31, 2018
Computer hardware and software	$ 301	$ 317
Furniture and fixtures	60	66
Machinery and equipment	745	939
Demonstration lasers and lasers placed with customers	483	1,151
Automobiles	154	200
Leasehold improvements	13	48
Construction in progress	178	—
	1,934	2,721
Accumulated depreciation	(775)	(870)
Property and equipment, net	$ 1,159	$ 1,851

Depreciation expense was $30,000 million and $0.1 million for the three months ended March 31, 2017 and 2018, respectively.

Note 5—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2017	March 31, 2018
Compensation and related benefits	$ 236	$ 291
Accrued warranty (Note 6)	87	56
Other accrued expenses	1	28
Accrued expenses	$ 324	$ 375

Note 6—Accrued Warranty

Activity in the product warranty accrual is included in accrued expenses above and consists of the following (in thousands):

	December 31, 2017	March 31, 2018
Balanced at beginning of period	$ 97	$ 87
Increase in warranty accrual	198	49
Claims satisfied	(208)	(80)
Accrued warranty	$ 87	$ 56

Warranty expense was $0.1 million for each of the three months ended March 31, 2017 and 2018, and is included in service and other cost of revenue in the accompanying statements of operations.

Note 7—Stockholders' Deficit

Common stock—The Company has one class of stock: common shares. The Company issued 56,080 shares of stock in exchange for $1.4 million that related to the private placements which took place during the three months ended March 31, 2018, respectively.

Note 8—Loss per Share

The Company calculates basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per share would reflect the effects of potentially dilutive securities, if any. For the three months ended March 31, 2017 and 2018, basic and diluted loss per share were the same.

Note 9—Stock-Based Compensation

In 2003, the Company adopted a stock option plan, which authorized the board of directors to grant stock option awards to eligible Optionees of the Company. In April 2012, such plan expired. In 2014, the Company established the 2014 Stock Option Plan whereby 1,000,000 shares of the Company's common stock were reserved for issuance to eligible Optionees. The 2014 Plan provided for the grant of

incentive stock options, non-statutory stock options, stock bonuses and rights to acquire restricted stock. Option awards under the 2014 Plan expired up to a maximum of 10 years from the date of the grant.

The Company concluded that option awards communicated to Optionees (the "Communicated Option Awards") were not validly authorized. Although the communicated awards were not outstanding options, the Company believes the communicated awards represented a contractual obligation to the Optionees, and the Company classified the option awards as liabilities in the financial statements.

Obligations under the Plans include time and performance-based awards. For time-based awards, vesting generally occurred over the service period of up to four years. Performance based awards vested at the time that the underlying performance conditions were met.

The liabilities for stock-based compensation awards were classified as a component of noncurrent liabilities on the balance sheet as the Company did not expect that such amounts will be settled through the use of current assets or through the creation of current liabilities.

On May 17, 2018, the Company's board of directors terminated the 2014 Stock Option Plan and on June 4, 2018, it was replaced with the 2018 Stock Compensation Plan (the "2018 Plan") whereby 3,300,000 shares of the Company's common stock were reserved for issuance. The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock and restricted stock units. On June 4, 2018, the Company's board of directors authorized replacement equity awards of stock options and on June 8, 2018, restricted stock units (the "Replacement Awards") to the Optionees. On various dates in June 2018, but after the board of directors authorization, the Replacement Awards were communicated to the Optionees in exchange for the cancellation of, and waiver to any claims related to, the Communicated Option Awards granted under the 2014 Plan which were determined to be not validly authorized. The issuance of the Replacement Awards and cancellation of the Communicated Option Awards was treated as a modification. The modification date is the date of the grant of the Replacement Awards, such date being June 4, 2018, for options and June 8, 2018, for restricted stock unit awards. The Company will recognize the remaining unrecognized compensation cost, as well as any incremental compensation cost of the Replacement Awards, over the remaining service period of the Replacement Awards. As the Replacement Awards have been determined to be equity awards, the Company will no longer record such awards as liabilities which are remeasured at fair value each reporting period.

The stock options granted as part of the Replacement Awards generally vest 33% at the first anniversary of the grant date with the balance vesting monthly over the remaining two years. The restricted stock units granted as part of the Replacement Awards include a service condition and a performance condition. The service condition generally begins on the grant date and continues through November 2019 and the restricted stock units vest at various times commencing the day following the expiration of the lock-up until November 2019. The performance condition relates to the Company completing its IPO and the vesting of the restricted stock units are contingent upon the achievement of such IPO.

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

A summary of the activity and related information of the Communicated Option Awards classified as liabilities and communicated during the three months ended March 31, 2018, is presented below:

	Awards	Weighted Average Exercise Price	Weighted Average Remaining Life	Aggregate Intrinsic Value
Outstanding at December 31, 2017	933,500	$ 3.92	3.57	$ 19,676
Granted	30,000	25.00	10.00	
Outstanding at March 31, 2018	963,500	$ 4.58	4.71	$ 19,676
Exercisable at March 31, 2018	769,507	$ 3.19	4.00	$ 14,015
Vested and expected to vest at March 31, 2018	963,500	$ 4.58	4.71	$ 19,676

No awards expired during the three months ended March 31, 2018.

Stock-based compensation expense recorded in operating expenses was as follows (in thousands):

	Three months ended March 31,	
	2017	2018
Selling, general and administrative	$ 350	$ 370
Research and development	38	78
Stock-based compensation in operating expenses	$ 388	$ 448

Stock-based compensation amounts of $38,000 and $0.1 million were capitalized to inventory during the three months ended March 31, 2017 and 2018, respectively.

These awards were presented as a stock-based compensation liability which was revalued at each reporting period with the change in fair value recorded to compensation expense. As of December 31, 2017, and March 31, 2018, the stock-based compensation liability was $15.4 million and $15.9 million, respectively. The fair value of the stock-based compensation liability was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted in the following table:

	Three months ended March 31,	
	2017	2018
Risk-free interest rate	1.44%	2.25%
Volatility	40.67%	44.00%
Expected dividend yield	0.00%	0.00%
Expected life	2.9	2.5

The weighted average fair value for awards granted during the three months ended March 31, 2017 and 2018, was $3.58 and $12.53, respectively. The Company's shares are not traded in any public market. The common stock value as of the date of grant was based on the share price of recent equity issuances, if available. If there were no such recent transactions, the Company's share valuation was estimated using both the income and market approaches, which were weighted 50% each. A discount of 35% was

then applied for lack of marketability for the Company's common stock. As of December 31, 2017, and March 31, 2018, the dates at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with third party investors who were not previous shareholders of the Company. The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period.

Note 10—Commitments and Contingencies

Capital stock transactions—The Company has determined that there have been defects with respect to certain capital stock transactions, including stock issuances and a reverse stock split, which were not effected in accordance with the requirements of applicable law. The Company could be subject to claims based on the defects. The Company believes any loss as a result of such defects is remote.

Legal—In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

Lease commitments—The Company has various noncancelable operating leases related to office spaces and manufacturing facilities in Carlsbad, California. In 2017, the Company entered into a new operating lease for office space and manufacturing facilities and abandoned its old leases. The Company recorded an expense and a corresponding liability of $0.2 million as a result of the lease abandonment, which represents the fair value of the lease termination costs upon initial measurement. The liability includes the estimated costs, net of estimated subleasing proceeds, the Company expects to incur during the lease term using the credit-adjusted risk-free interest rate. The initial expense is included in selling, general and administrative expenses in the accompanying statement of operations. The initial liability measured at fair value less amortization is included in accrued expenses and other liabilities on the accompanying balance sheet as of December 31, 2017, and March 31, 2018. In periods subsequent to initial measurement, changes to the liability will be measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

Some of these agreements have escalating rent payment provisions. Rent expense under such agreements is recognized on a straight-line basis. Total rent expense for the three months ended March 31, 2017 and 2018, was $0.1 million and $0.1 million, respectively.

Future minimum rental payments due are as follows (in thousands):

Years Ending December 31,	
2018 (remaining 9 months)	$ 377
2019	500
2020	514
2021	529
2022	432
Thereafter	2,363
Total	$4,715

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

Note 11—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the dermatology segment and the vascular segment.

In deciding how to allocate resources and assess performance, the Company's chief operating decision maker regularly evaluates the sales and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to the Company and not specific to a particular segment; therefore, these amounts are not evaluated by the Company's chief operating decision maker on a segmented basis.

The following tables summarize segment performance for the three months ended March 31, 2017 and 2018 (in thousands):

	Three months ended March 31,	
	2017	2018
Vascular	$ —	$ 90
Dermatology	1,065	879
Net revenue	$ 1,065	$ 969
Vascular	$ —	$ 251
Dermatology	602	485
Cost of revenue	$ 602	$ 736
Vascular	$ —	$ (161)
Dermatology	463	394
Gross profit	$ 463	$ 233

Generally, all assets are common assets, except for demonstration lasers and lasers placed with customers, which are a subset of property and equipment. Demonstration lasers and lasers placed with customers aggregated in the vascular segment was $0.2 million and $0.5 million as of December 31, 2017, and March 31, 2018, respectively. Demonstration lasers and lasers placed with customers aggregated in the dermatology segment was $0.3 million and $0.7 million as of December 31, 2017, and March 31, 2018, respectively.

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

No sales to an individual customer or country other than the United States accounted for more than 10% of net revenue for the three months ended March 31, 2017 or 2018. Net revenue, classified by the major geographic areas in which our customers are located, was as follows:

	Three months ended March 31,	
	2017	2018
United States	$1,002	$829
All other countries	63	140
Net revenue	$1,065	$969

Note 12—Subsequent Events

The Company has evaluated subsequent events through June 27, 2018, the date these financial statements were issued.

Private Placement Financing—From April 2018 through May 2018, the Company issued 260,000 shares of common stock at a per share price of $25 for aggregate proceeds of $6.5 million in connection with a private placement financing.

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Shares

RA MEDICAL SYSTEMS, INC.

PROSPECTUS

Piper Jaffray **Cantor**

SunTrust Robinson Humphrey

Nomura

, 2018

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses to be paid by the Registrant, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the SEC registration fee, the FINRA filing fee, and the exchange listing fee.

	Amount to be Paid
SEC registration fee	$ 10,738.13
FINRA filing fee	$ 13,437.50
The New York Stock Exchange listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ 24,175.63

* To be provided by amendment

Item 14. Indemnification of Directors and Officers.

On completion of this offering, as permitted by Section 102(b)(7) of the Delaware General Corporation Law, the Registrant's amended and restated certificate of incorporation and amended and restated bylaws will contain provisions that eliminate the personal liability of the Registrant's directors and executive officers for monetary damages for breach of their fiduciary duties as directors or officers.

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, executive officer, employee or agent of the corporation or is or was serving at the request of a corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, the amended and restated certificate of incorporation and amended and restated bylaws of the Registrant will provide that:

The Registrant shall indemnify its directors and officers for serving the Registrant in those capacities or for serving other business enterprises at the Registrant's request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best

interests of the Registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

The Registrant may, in its discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

The Registrant is required to advance expenses, as incurred, to its directors and officers in connection with defending a proceeding, except that such director or officer shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

The Registrant will not be obligated pursuant to the amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person, except with respect to proceedings authorized by the Registrant's board of directors or brought to enforce a right to indemnification.

The rights conferred in the amended and restated certificate of incorporation and amended and restated bylaws are not exclusive, and the Registrant is authorized to enter into indemnification agreements with its directors, officers, employees, and agents and to obtain insurance to indemnify such persons.

The Registrant may not retroactively amend the bylaw provisions to reduce its indemnification obligations to directors, officers, employees, and agents.

The Registrant has entered into indemnification agreements with its directors and executive officers that provide the maximum indemnity allowed to directors and executive officers by Section 145 of the Delaware General Corporation Law and also to provide for certain additional procedural protections, in addition to the indemnification provided for in its amended and restated certificate of incorporation and bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The Registrant has purchased and currently intends to maintain insurance on behalf of each and any person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The Underwriting Agreement (Exhibit 1.1 hereto) provides for indemnification by the underwriters of the Registrant and its executive officers and directors, and by the Registrant of the underwriters, for certain liabilities, including liabilities arising under the Securities Act.

See also the undertakings set out in response to Item 17 herein.

Item 15. Recent Sales of Unregistered Securities.

Since January 1, 2015, the Registrant has issued and sold the following securities:

Common Stock Issuances

(a) From August 2016 to May 2017 the Registrant sold 667,500 shares of its common stock, at a purchase price of $8.00 per share, to investors in connection with its 2016 financing for aggregate cash consideration of $5.3 million.

(b) On August 30, 2016, the Registrant issued 16,649 shares of its common stock to a service provider as consideration for services rendered.

(c) From September 2017 to May 2018 the Registrant sold 731,280 shares of its common stock, at a purchase price of $25.00 per share, to investors in connection with its 2017 financing for aggregate cash consideration of $18.3 million.

The offers, sales, and issuances of the securities described in Items 15(a), 15(b), and 15(c) were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. With respect to the offers, sales, and issuances of the securities described in Items 15(a) and 15(c), all purchasers were "accredited investors" as that term is defined under Item 501 of Regulation D. In each case, the issuances were made, without any general solicitation or advertising, to a limited number of sophisticated purchasers with knowledge and experience of financial and business matters related to an investment in the Company's securities. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Each of the purchasers of securities had adequate access, through employment, business or other relationships, to information about the Registrant.

Option and Restricted Stock Unit Issuances—Non-Executive Employees

Pursuant to the terms of its 2018 Stock Compensation Plan, the Registrant granted to its non-executive employees, consultants and other service providers (i) options to purchase an aggregate of 680,900 shares of its common stock at exercise prices of $28.94 per share on June 4, 2018; and (ii) 481,906 restricted stock units effective June 8, 2018.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Registrant believes the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The sales of these securities were made without any general solicitation or advertising.

Option and Restricted Stock Unit Issuances—Executive Officers and Directors

Pursuant to the terms of its 2018 Stock Compensation Plan, the Registrant granted to certain of its officers and directors (i) options to purchase an aggregate of 1,221,000 shares of its common stock at exercise prices of $28.94 per share on June 4, 2018; and (ii) 858,926 restricted stock units effective June 8, 2018.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Registrant believes the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder because the issuance of securities to the recipients did not involve a public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof. All recipients had adequate access, through their relationships with the Registrant, to information about the Registrant. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
1.1*	Form of Underwriting Agreement.
3.1	Certificate of Incorporation of the Registrant, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the completion of this offering.
3.3	Bylaws of the Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the completion of this offering.
4.1	Specimen common stock certificate of the Registrant.
5.1*	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
10.1	Lease Agreement by and between the Registrant and Lloyd Wells Gift Trust dated November 24, 1987, for the premises located at 2070 Las Palmas Drive, Carlsbad, California 92011 dated as of August 17, 2017.
10.2*+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.3+	Ra Medical Systems, Inc. 2018 Stock Compensation Plan and Forms of Award Agreement thereunder.
10.4*+	Ra Medical Systems, Inc. 2018 Equity Incentive Plan and Forms of Award Agreement thereunder.
10.5*+	Ra Medical Systems, Inc. 2018 Employee Stock Purchase Plan.
10.6*+	Ra Medical Systems, Inc. Executive Incentive Compensation Plan.
10.7+	Ra Medical Systems, Inc. Form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement for executive officers.
10.8+	Change in Control and Severance Agreement, by and between the Registrant and Dean Irwin, dated as of July 13, 2018.
10.9+	Change in Control and Severance Agreement, by and between the Registrant and Melissa Burstein, dated as of July 13, 2018.
10.10+	Change in Control and Severance Agreement, by and between the Registrant and Jeffrey Kraws, dated as of July 13, 2018.
10.11+	Change in Control and Severance Agreement, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018.
10.12+	Confirmatory Employment Letter, by and between the Registrant and Dean Irwin, dated as of July 13, 2018.
10.13+	Confirmatory Employment Letter, by and between the Registrant and Melissa Burstein, dated as of July 13, 2018.
10.14+	Confirmatory Employment Letter, by and between the Registrant and Jeffrey Kraws, dated as of July 13, 2018.
10.15+	Confirmatory Employment Letter, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018.

Exhibit Number	Description
21.1	List of Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP Independent Registered Public Accounting Firm.
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1	Power of Attorney (see the signature page to this Form S-1).

* To be filed by amendment.
+ Indicates management contract or compensatory plan.

(b) Financial Statement Schedules.

All financial statement schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or related notes.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing as specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Carlsbad, State of California, on July 16, 2018.

RA MEDICAL SYSTEMS, INC.

By: /s/ Dean Irwin
Dean Irwin
Chief Executive Officer, Co-President, Chief Technology Officer, Chairman of the Board of Directors
(Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dean Irwin and Andrew Jackson, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities (including his or her capacity as a director and/or officer of Ra Medical Systems, Inc.), to sign any and all amendments (including post-effective amendments or any abbreviated registration statement and any amendments thereto filed) to this Registration Statement, and to sign any and all additional registration statements for the same offering covered by this Registration Statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as they, he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated below:

Signature	Title	Date
/s/ Dean Irwin **Dean Irwin**	Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors (Principal Executive Officer)	July 16, 2018
/s/ Andrew Jackson **Andrew Jackson**	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	July 16, 2018
/s/ Melissa Burstein, M.B.A. **Melissa Burstein, M.B.A.**	Executive Vice President and Director	July 16, 2018
/s/ Martin Burstein, M.B.A. **Martin Burstein, M.B.A.**	Director	July 16, 2018

Signature	Title	Date
/s/ Richard Heymann **Richard Heymann**	Director of Corporate Strategy and Business Development, and Director	July 16, 2018
/s/ Maurice Buchbinder, M.D. **Maurice Buchbinder, M.D.**	Director	July 16, 2018
/s/ Martin Colombatto **Martin Colombatto**	Director	July 16, 2018
/s/ Richard Mejia, Jr. **Richard Mejia, Jr.**	Director	July 16, 2018

EXHIBIT C

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As filed with the Securities and Exchange Commission on August 24, 2018

Registration No. 333-226191

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT

Under

The Securities Act of 1933

Ra Medical Systems, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	3841	38-3661826
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2070 Las Palmas Drive
Carlsbad, California 92011
(760) 804-1648
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Dean Irwin
Chief Executive Officer, Chairman of the Board, Co-President, and Chief Technology Officer
Ra Medical Systems, Inc.
2070 Las Palmas Drive
Carlsbad, California 92011
(760) 804-1648
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Martin J. Waters
Wilson Sonsini Goodrich & Rosati, P.C.
12235 El Camino Real,
San Diego, California 92130
(858) 350-2300

Joshua A. Kaufman
Divakar Gupta
Charles Bair
Cooley LLP
1114 Avenue of the Americas
New York, New York 10036
(212) 479-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[1][2]	Amount of Registration Fee[3]
Common Stock $0.0001 par value per share	$86,250,000	$10,738.13

(1) Includes offering price of any additional shares that the underwriters have the option to purchase.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(3) The registrant previously paid a registration fee of $10,738.13 with the initial filing of this registration statement.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **(Subject to Completion, Dated August 24, 2018)**

Shares

Common Stock

This is the initial public offering of shares of common stock by Ra Medical Systems, Inc. No public market for our common stock currently exists. We are offering all of the shares of common stock offered by this prospectus. We expect the initial public offering price to be between $ and $ per share.

We have applied to list our common stock on the New York Stock Exchange under the symbol "RMED."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common shares in "Risk factors" beginning on page 13 of this prospectus.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts[1]	$	$
Proceeds, before expenses, to us	$	$

(1) We refer you to "Underwriting" beginning on page 155 for additional information regarding total underwriting compensation.

The underwriters may also purchase up to an additional shares of common stock from us at the public offering price, less the underwriting discounts payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus.

The underwriters expect to deliver the shares of common stock to investors on or about , 2018.

Piper Jaffray **Cantor**

SunTrust Robinson Humphrey

Nomura **Maxim Group LLC**

, 2018

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Through and including (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

For investors outside the U.S.: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the U.S. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary may not contain all the information you should consider before investing in our common stock. You should carefully read this prospectus in its entirety before investing in our common stock, including the sections titled "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" and our financial statements and related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms "Ra Medical," "Ra Medical Systems," "the Company," "our company," "we," "us," and "our," refer to Ra Medical Systems, Inc.

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of the DABRA laser system and disposable catheter, together referred to as DABRA, in the United States. Following the temporary placement period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements or DABRA laser placement acknowledgments with each customer, which we refer to collectively as Usage Agreements. As of June 30, 2018, we had a U.S. installed base of 31 DABRA laser systems, eight of which have signed Usage Agreements with us, and the remainder of which are temporarily placed for use in demonstrations, trials, or training. DABRA is cleared by the U.S. Food and Drug Administration, or FDA, as a tool for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease, which includes peripheral artery disease, or PAD, which commonly occurs in the legs. We intend to pursue additional uses for DABRA, including seeking regulatory clearance for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other venous and arterial occlusions, or blockages in the veins or arteries. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA. DABRA is our minimally-invasive excimer laser and disposable catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and

obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging.

DABRA is a novel technology for use in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease. We believe that our liquid-filled, full aperture ratio catheter allows for a less traumatic endovascular treatment for the removal of vascular blockages and offers significant benefits over competing treatments and therapies. DABRA is easy to use and can cross and debulk, or reduce or remove, a broad range of blockage types without the use of a guidewire. Although DABRA is suitable for use as a monotherapy, or a therapy that uses one type of treatment, it is predominantly used with angioplasty balloons and also can be used adjunct to drug-eluting balloons, stents, and other endovascular treatments.

In May 2017, we received FDA 510(k) clearance to market the DABRA laser system and disposable DABRA catheter in the U.S. for intended use in ablating a channel in occlusive peripheral vascular disease. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of DABRA in the United States. We market DABRA in the U.S. through our direct sales force comprised of 15 sales representatives as of June 30, 2018, which places lasers in catheterization laboratories that perform high volumes of endovascular procedures, including atherectomy on peripheral arteries. We have plans to increase sales by further expanding this organization. DABRA was granted CE mark clearance in September 2016, and we sell systems through distributors in select non-U.S. countries.

Pharos. Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. We have also received clearance to market Pharos from the European Medicines Agency, or EMA, China Food and Drug Administration, or CFDA, and South Korea Ministry of Drug Safety, or KFDA in the applicable jurisdictions. Pharos offers significant benefits to patients. The targeted nature of our treatment allows the operator to spare healthy tissue from exposure to the ultraviolet light making the treatment faster and safer than some other forms of phototherapy, or light therapy. The light induces T-cell apoptosis, or cell death, which we believe may produce an immunosuppressant effect.

Our Strategy

Our goal is to become the leading medical device company marketing excimer lasers as tools for the treatment of endovascular diseases. Key elements of our strategy to achieve this goal are:

- ***Driving physician awareness of DABRA.*** Our program to educate physicians regarding DABRA's value proposition consists of presentations and exhibits at industry conferences, advertising in medical journals, direct visits, webinars, and calls.
- ***Creating patient awareness of DABRA.*** We are establishing marketing and support programs with physicians and patient advocacy organizations to create patient awareness of PAD treatment options in order to generate demand for our products.
- ***Expanding DABRA sales.*** We provide physicians with clinical training to drive adoption and utilization of DABRA. We believe that a strong sales team to train physicians on the use and the benefits of DABRA will increase sales. We expect to continue to expand the clinical sales team through 2018 and beyond.

- ***Extending DABRA to additional indications.*** We plan to leverage our product technology and research and development expertise to develop DABRA for additional vascular indications, such as CAD and in-stent restenosis.
- ***Expanding commercial opportunities for DABRA internationally***. We received the right to affix the CE mark to DABRA in the third quarter of 2016, permitting DABRA to be marketed and sold in Europe and other CE mark markets. We plan to expand commercial opportunities for DABRA internationally through obtaining additional regulatory approvals and expanding our relationships with international distributors.
- ***Optimizing existing manufacturing capabilities to generate operating leverage***. We design, develop and manufacture DABRA in-house using components and sub-assemblies provided by third-party suppliers. We believe that by controlling the manufacturing and assembly of our products we are able to innovate more quickly, produce higher quality products, and increase our manufacturing scale in a cost-effective manner. We intend to use our design, engineering, and manufacturing capabilities to further improve the efficiency of our manufacturing process and expand our margins.
- ***Expanding our product offerings.*** We believe that we will be able to leverage our technology and sales platform to expand our endovascular offerings with ancillary endovascular devices such as angioplasty balloons, guide catheters, and introducers. We intend to achieve this through our internal development efforts and with selective licenses, alliances or acquisitions of complementary products, technologies or businesses.

Strengths of our Approach—DABRA

DABRA includes a portable excimer laser system combined with proprietary, single-use catheters that together represent a competitive atherectomy solution for the minimally invasive endovascular treatment of blockages in the vasculature, or blood vessels such as arteries or veins. DABRA represents a novel approach to the treatment of a broad range of vascular blockages that is safe and effective, easy to use, and competitively priced. We believe that the principal benefits of DABRA are:

- ***Safety.*** DABRA is designed to track the patient's true lumen, or the center of the artery, and not to penetrate between the layers of arterial structure known as the subintimal space. Damage or stretching of the arterial walls, which can lead to dissection, or a tear in the inner lining of the vessel wall, or perforation, or a hole or a break in the vessel wall, may be reduced. No serious adverse events were reported in our 2017 pivotal study, which followed 38 subjects for 180 days, or reported in our post-market surveillance for DABRA. In our post-market surveillance, the most frequent complication reported to us has been clinically non-significant vessel perforation.
- ***Efficacy.*** Unlike many treatments for PAD that do not remove plaque, DABRA employs photochemical ablation, or the removal of body tissue by using photons, to disintegrate plaque by breaking its chemical bonds, thereby reducing the plaque to the components of its fundamental chemistry without generating potentially harmful particulates. We believe that eliminating plaque while minimizing injury to the arterial wall may minimize the rate of restenosis, or the re-accumulation of blockages. We followed 38 subjects from our pivotal study to 180 days thereafter and all of the

subjects were determined to be completely free of target lesion revascularization, or the need to retreat the lesion.

- ***Utility.*** DABRA enables physicians to remove plaque from long and calcified lesions in arteries located in the lower extremities both above- and below-the-knee. DABRA is able to cross and debulk a wide variety of plaque, removing vascular blockages that other products are unable to cross without the use of a guidewire. For example, in patients with a chronic total occlusion, or CTO, the physician may use DABRA to cross the CTO prior to alternative treatments consisting of balloon angioplasty and possibly stenting.
- ***Ease of Use.*** DABRA employs techniques similar to those used in angioplasty, which are familiar to the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the U.S. who are generally trained in endovascular techniques. This significantly increases the number of physicians who are able to perform the procedure compared to surgical alternatives that must be performed by highly-trained vascular surgeons.
- ***Cost and Time Efficient.*** We believe that because our single-use DABRA catheters are priced competitively and because we provide the DABRA laser system for a nominal periodic fee without requiring the purchase of capital equipment, DABRA is a cost-effective solution for providers. Providers are also eligible for reimbursement for procedures that are performed using DABRA by using existing Current Procedural Terminology, or CPT, codes. In addition, DABRA's easy setup and fast ablation speed reduce both treatment and fluoroscopy time, or x-ray exposure time, for the patient, physician, and staff, improving the providers' patient throughput. The average lasing time in our pivotal study was approximately two and a half minutes per procedure.
- ***Immunotherapeutic Benefits.*** Research performed using 308 nanometer laser energy, the wavelength of Pharos, demonstrated increased T-cell apoptosis, which may produce an immunosuppressant effect. Unlike with Pharos, where we can measure the degree and speed of clearance of disease and quantify the remission time, with DABRA we have not established the benefits of this immunosuppressant effect in the vasculature. We intend to conduct a registry or study to identify any immunotherapeutic benefits.

Strengths of our Approach—Pharos

Pharos is an excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders, such as psoriasis, vitiligo, atopic dermatitis, and leukoderma. We believe that the principal benefits of Pharos are:

- ***Wavelength.*** Studies have shown that the action spectrum, or the rate of a physiological activity plotted against wavelength of light, for immunologically modulated skin disorders is centered at about 308 nanometers. Pharos is a 308 nanometer laser, making it ideally suited for use as a tool in the treatment of these disorders.
- ***Energy.*** The energy from excimer lasers has been shown, in both in vivo and in vitro studies, to have almost four times the T-cell apoptosis generation than non-laser sources. Pharos is a pulsed laser capable of producing very high peak powers and we believe that this may produce an immunosuppressive effect.

- ***Collimation.*** Ultraviolet-B light has a very shallow penetration into the skin, typically less than 100 microns. Although the skin tends to scatter the light, collimation, or keeping the light rays parallel, helps prevent reflection and improves the dose delivery. Pharos has a moderately collimated beam and this collimation allows for treatment in intertriginous areas, such as the groin and armpits, and mucosal areas, such as the mouth and ears, without compromising dose.
- ***Targeting.*** Applying the laser energy only to the diseased tissue not only spares the healthy tissue from exposure, but also allows the operator to increase the dose to the affected areas. We believe that Pharos is the only system that has an integrated adjustable spot size offering continuous beam adjustment from a large square to a small circle.
- ***Footprint.*** Dermatological treatment rooms are small and often crowded with other equipment. Pharos has a small footprint and is among the lightest excimer lasers currently marketed, allowing physicians to conserve space and easily move the system.

Risks Associated with our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section captioned "*Risk factors*" immediately following this prospectus summary. You should read these risks before you invest in our common stock. In particular, risks associated with our business include, but are not limited to, the following:

- We have incurred losses in each of the last two years and may be unable to achieve profitability in the future.
- We may be unable to achieve revenue growth.
- Our success depends in large part on DABRA. If we are unable to successfully market and sell DABRA, our business prospects will be significantly harmed.
- We will require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms, or at all. As a result, we may not be able to continue our marketing efforts to increase the adoption of our products.
- Our products may not gain or maintain market acceptance among physicians and patients and others in the medical community.
- The continuing development of our products depends upon our maintaining strong working relationships with physicians.
- If our manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to manufacture and sell our products and to pursue our research and development efforts may be jeopardized.
- We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us.
- If DABRA and Pharos are not approved for new indications, our commercial opportunity will be limited.
- If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our existing products and any new products we may develop, and our technology may be adversely affected.

- Third parties may claim that the manufacture, use or sale of our products infringe their intellectual property rights.
- Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business.
- Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.
- We may not be able to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and acceptable market share for DABRA and Pharos.
- If critical components used in manufacturing our products become scarce or unavailable, we may incur increased costs and delays in the manufacturing and delivery of our products, which could damage our business.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.
- We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Corporate and other Information

We were incorporated in California on September 4, 2002, and reincorporated in Delaware in July 2018. Our principal executive offices are located at 2070 Las Palmas Drive, Carlsbad, California 92011 and our telephone number is (760) 804-1648 or (877) 635-1800 toll-free. Our corporate website address is www.ramed.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

We own or have rights to trademarks that we use in connection with the operation of our business. Ra Medical Systems, Inc. and our logo as well as other trademarks such as DABRA and Pharos, are used in this prospectus. Solely for convenience, the trademarks referred to in this prospectus are listed without trademark symbols, but we will assert, to the fullest extent under applicable law, our rights to these trademarks. Additionally, we do not intend for our use or display of other companies' trademarks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

Implications of being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, enacted in April 2012. An "emerging growth company" may take

advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of "Selected financial data" and related "Management's discussion and analysis of financial condition and results of operations" in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares
Underwriters' option to purchase additional shares	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to an additional shares of common stock from us.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately $ million based upon an assumed initial public offering price of $ per share, the mid-point of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering for the expansion of our direct sales force and marketing of our products, to support clinical studies for new products and product enhancements including for expanded indications, and to support other research and development activities, working capital, and general corporate purposes. We may also use a portion of the net proceeds of this offering for acquisitions to bolster our product offerings. We have not entered into any agreements or commitments with respect to any specific acquisitions and have no understandings or agreements with respect to any such acquisition or investment at this time. See "*Use of proceeds*" for additional information.
Risk factors	You should carefully read the "*Risk factors*" section of this prospectus beginning on page 13 for a discussion of factors that you should consider before deciding to invest in our common stock.
Proposed New York Stock Exchange trading symbol	"RMED"

The number of shares of our common stock to be outstanding after this offering is based on 8,204,251 shares of our common stock outstanding as of June 30, 2018, and excludes:

- 1,898,000 shares of common stock issuable upon exercise of options outstanding as of June 30, 2018, that were issued at an exercise price of $28.94 per share under our 2018 Stock Compensation Plan, or our Compensation Plan;

- 1,340,301 shares of common stock issuable upon the vesting and settlement of restricted stock units outstanding as of June 30, 2018, that were issued under our Compensation Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of:
  - 61,699 shares of common stock reserved for future issuance under our Compensation Plan as of June 30, 2018, which shares will be added to the shares to be reserved under our 2018 Equity Incentive Plan, or our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for future issuance under our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for issuance under our 2018 Employee Stock Purchase Plan, or ESPP, which will become effective upon the completion of this offering; and
  - any shares that become available for future issuance under our 2018 Plan and ESPP, pursuant to provisions that automatically increase the reserves under such plans each year.

Unless otherwise noted, the information in this prospectus assumes:

- a -for- forward split of our common stock to be effected before the closing of this offering;
- the filing of our amended and restated certificate of incorporation immediately prior to the closing of this offering;
- no exercise of outstanding options subsequent to June 30, 2018; and
- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock in this offering.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data for the periods and as of the dates indicated. We have derived the statements of operations data for the years ended December 31, 2016 and 2017 from our audited financial statements included elsewhere in this prospectus. We have derived the statements of operations data for the six months ended June 30, 2017 and 2018, and the balance sheet data as of June 30, 2018 from our unaudited interim condensed financial statements included elsewhere in this prospectus. We have prepared the unaudited interim financial statements on the same basis as the audited financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future and the results for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the full year or any other period. You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the sections titled "*Selected financial data*" and "*Management's discussion and analysis of financial condition and results of operations*."

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
	(in thousands, except per share data)			
Statement of Operations Data:				
Net revenue	$ 5,976	$ 5,870	$ 2,643	$ 2,205
Cost of revenue	3,138	4,165	1,813	1,726
Gross profit	2,838	1,705	830	479
Operating expenses:				
Selling, general and administrative	5,321	14,947	10,028	10,254
Research and development	1,715	4,518	3,746	1,308
Total operating expenses	7,036	19,465	13,774	11,562
Operating loss	(4,198)	(17,760)	(12,944)	(11,083)
Interest expense	3	4	2	2
Income tax expense	1	1	1	3
Net loss	(4,202)	(17,765)	(12,947)	(11,088)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.60)	$ (2.35)	$ (1.73)	$ (1.38)
Weighted-average shares outstanding, basic and diluted	6,951	7,545	7,464	8,020

	As of June 30, 2018	
	Actual	As Adjusted[1] [2]
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 9,769	$
Working capital[3]	6,109	
Total assets	16,605	
Accumulated deficit	(40,477)	
Total stockholders' equity	9,778	

footnotes on following page

(1) As adjusted amounts reflect the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) A $1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming the number of shares offered by us as stated on the cover of this prospectus remain unchanged and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities.

The as adjusted information discussed above is illustrative only and will be revised based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

Non-GAAP Measures

EBITDA and Adjusted EBITDA are performance measures that provide supplemental information we believe is useful to analysts and investors to evaluate our ongoing results of operations, when considered alongside other GAAP measures. These non-GAAP Measures exclude the financial impact of items management does not consider relevant in assessing our ongoing operating performance, and thereby facilitate review of our operating performance on a period-to-period basis. Comparability to our results of operations to other companies may be impacted by our stock-based compensation which was classified as a liability and revalued at each reporting period with the change in fair value recorded to compensation expense in the statement of operations.

We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. Some of these limitations are that:

- EBITDA excludes certain recurring, non-cash charges such as deprecation of fixed assets and amortization of acquired intangible assets and, although these are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future; and
- Adjusted EBITDA further excludes stock-based compensation expense, which has been, and will continue to be for the foreseeable future, a significant recurring expense in our business and an important part of our compensation strategy, as well as certain non-recurring items which may affect comparability of our core operations such as the loss on abandonment of facility.

In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison.

A reconciliation for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with U.S. GAAP is included below. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single

financial measure to evaluate our business. We define Adjusted EBITDA as our GAAP net loss as adjusted to exclude depreciation, amortization, interest expense, income tax expense, stock-based compensation and loss on abandonment of facility.

The following table presents a reconciliation of Adjusted EBITDA to net loss, the most comparable GAAP financial measure, for each of the periods presented:

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
	(in thousands)			
Statement of Operations Data:				
Net loss	$(4,202)	$(17,765)	$(12,947)	$(11,088)
Depreciation and amortization	95	218	86	231
Interest expense	3	4	2	2
Income tax expense	1	1	1	3
EBITDA	(4,103)	(17,542)	(12,858)	(10,852)
Stock-based compensation	2,300	12,706	10,884	5,204
Loss on abandonment of facility	—	212	—	—
Adjusted EBITDA	$(1,803)	$ (4,624)	$ (1,974)	$ (5,648)

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all of the other information contained in this prospectus, including our financial statements and related notes, before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to our Business and Products

We have incurred losses in each of the last two years and may be unable to achieve profitability in the future.

We incurred net losses of $4.2 million and $17.8 million for the years ended December 31, 2016 and 2017, respectively, and $12.9 million and $11.1 million for the six months ended June 30, 2017 and 2018, respectively. As of June 30, 2018, we had an accumulated deficit of $40.5 million. We expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand our marketing efforts to increase adoption of our products and expand existing relationships with our customers, to obtain regulatory clearances or approvals for our products in additional jurisdictions and for additional indications, and to develop new products or add new features to our existing products. In addition, we expect our general and administrative expenses to increase following this offering due to the additional costs associated with being a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenues in order to achieve and sustain profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or return to profitability would have a material adverse effect on our business, financial condition, and results of operations and could negatively impact the value of our common stock.

We may be unable to achieve revenue growth.

Our ability to grow our revenue in future periods will depend on our ability to successfully penetrate our target markets and increase sales of our products and any new product indications that we introduce, which will, in turn, depend in part on our success in growing our installed unit base and driving continued use of our systems. New product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies to drive revenue growth. If we cannot achieve revenue growth, it could have a material adverse effect on our business, financial condition, and results of operations.

Our success depends in large part on DABRA. If we are unable to successfully market and sell DABRA, our business prospects will be significantly harmed.

Our future financial success will depend substantially on our ability to effectively and profitably market and sell DABRA. The commercial success of DABRA will depend on a number of factors, including the following:

- the effectiveness of our and our distributors' marketing and sales efforts in the U.S. and abroad, including our efforts to build out our sales team;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing treatments;

- the availability of coverage and adequate levels of reimbursement under private and governmental health insurance plans for DABRA-based procedures;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to DABRA;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to DABRA;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices, or cGMP; and
- whether we are required by the FDA, EMA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

If we fail to successfully market and sell DABRA, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition, and results of operations.

We will require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. As a result, we may not be able to continue our marketing efforts to increase the adoption of our products.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and marketing efforts. We expect our sales and marketing expenses to increase substantially in connection with our plan to commercialize DABRA in the U.S. and internationally. These expenditures will also include costs associated with manufacturing and supply, sales and marketing costs, and general operations. In addition, other unanticipated costs may arise.

As of June 30, 2018, we had cash and cash equivalents of $9.8 million. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months.

The amount and timing of any expenditures needed to implement our sales and marketing programs will depend on numerous factors, including, but not limited to:

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and acceptable market share for DABRA and Pharos;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- the emergence of competing technologies and other adverse market developments;
- the costs associated with manufacturing, selling, and marketing DABRA and Pharos for their cleared or approved indications or any other indications for which we receive regulatory clearance or approval, including the cost and timing of expanding our manufacturing capabilities, as well as establishing our sales and marketing capabilities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, our future products or future improvements on our existing products, if any;

- the time and cost necessary to complete post-marketing studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, as we become a public company.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our products, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend our sales and marketing efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

Our products may not gain or maintain market acceptance among physicians and patients and others in the medical community.

Our success will depend, in part, on the acceptance of our products as safe, useful and, with respect to physicians, cost effective. We cannot predict how quickly, if at all, catheterization laboratories and physicians will accept our products or, if accepted, how frequently they will be used. Patients and their care providers must believe our products offer benefits over alternative treatment methods. Additional factors that will influence whether our products gain and maintain market acceptance, include:

- whether physicians, catheterization laboratory owners and operators, patients, and others in the medical community consider our products safe, effective, and cost effective treatment methods;
- the potential and perceived advantages of our products over alternative treatment methods;
- the prevalence and severity of any side effects associated with using our products;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities;
- limitations or warnings contained in the labeling cleared or approved by the FDA, EMA or other authorities;
- the cost of treatment in relation to alternative treatments methods;
- the convenience and ease of use of DABRA and Pharos relative to alternative treatment methods;
- pricing pressure, including from group purchasing organizations, or GPOs, seeking to obtain discounts on DABRA and Pharos based on the collective buying power of the GPO members;
- the availability of adequate coverage, reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;

- our ability to provide incremental clinical and economic data that shows the safety and clinical efficacy and cost effectiveness of, and patient benefits from, our products; and
- the effectiveness of our sales and marketing efforts for DABRA and Pharos.

If we do not educate physicians about PAD and the existence of our products, DABRA may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for CAD. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost effective. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition, and results of operations.

The continuing development of our products depends upon our maintaining strong working relationships with physicians.

The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the U.S. Department of Justice, or DOJ. Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations. Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below in the Risk Factor captioned *"Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings."*

Physicians and staff may not commit enough time to sufficiently learn how to use our products.

In order for physicians and staff to learn to use our products, we encourage physicians to attend structured training sessions in order to familiarize themselves with our technology. There are many nuances to using our products as intended. For example, the DABRA catheter is fragile and may be prone to bending at the entry of the artery, a problem known as kinking. Further, physicians and their staff must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use our products. Market acceptance of DABRA could be delayed by lack of physician or staff willingness to attend training sessions or familiarize themselves with DABRA. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse effect on our business, financial condition, and results of operations.

If our sole manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to manufacture and sell our products and to pursue our research and development efforts may be jeopardized.

We currently manufacture and assemble our products in our sole manufacturing facility in Carlsbad, California. Our products consist of components sourced from a variety of suppliers, with final assembly completed at our facility. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, fires, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, extreme weather conditions, medical epidemics, and other natural or man-made disasters or other business interruptions, for which we are predominantly self-insured. Any of these may render it difficult or impossible for us to manufacture products for an extended period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products. We also rely on third-party component suppliers, and our ability to obtain commercial supplies of our products could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, which would have a material adverse effect on our business, financial condition, and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products.

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians in connection with the use of our products on patients. If these physicians are not properly trained or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;

- exhaustion of any available insurance and our capital resources;
- the inability to market and sell our products; and
- a decline in the price of our common stock.

We believe our product liability insurance is customary for similarly situated companies, but it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us.

The medical device industry is intensely competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may also develop products that are more effective, more convenient, more widely used, less costly, or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology, which would have a material adverse effect on our business, financial condition, and results of operations.

We may be unable to compete successfully with larger companies in our highly competitive industry.

The healthcare industry is highly competitive. There are numerous approved products for treating vascular and dermatological diseases in the indications in which we have received clearance or approval and those that we may pursue in the future. Many of these cleared or approved products are well-established and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future.

Our primary competitors for DABRA include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., or Philips, including Volcano Corporation and Spectranetics Corporation, including products from the C.R. Bard acquisition, and Abbott Laboratories. These companies are manufacturers of products used in competing therapies within the peripheral and coronary atherectomy markets such as:

- atherectomy, using mechanical methods to remove vascular blockages;
- balloon angioplasty and stents;

- specialty balloon angioplasty, such as scoring balloons, pillowing balloons, cutting balloons and drug-coated balloons;
- bypass surgery; and
- amputation.

We are also subject to competition from pharmaceutical companies that produce drugs which aim to destroy plaque or remove blockages in the bloodstream.

Our primary competitors for Pharos are Daavlin, National Biological, STRATA Skin Sciences and large pharmaceutical companies producing biologicals used in the treatment of chronic skin conditions.

Many of our competitors have substantially greater financial, manufacturing, commercial, and technical resources than we do. There has been consolidation in the industry, and we expect that to continue. Larger competitors may have substantially larger sales and marketing operations than we do. This may allow those competitors to spend more time with current and potential customers and to focus on a larger number of current and potential customers, which gives them a significant advantage over our sales and marketing team and our international distributors in making sales. In addition, we are often selling to customers who already utilize our competitors' products and who have established relationships with our competitors' sales representatives and familiarity with our competitors' products.

Larger competitors may also have broader product lines, which enables them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical trials, obtaining FDA and non-U.S. regulatory clearances or approvals and marketing cleared or approved products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. This may render our technology or products obsolete or noncompetitive. Our competitors may also be better equipped than we are to respond to competitive pressures. If we are unable to compete successfully in our industry, it would have a material adverse effect on our business, financial condition, and results of operations.

If DABRA and Pharos are not approved for new indications, our commercial opportunity will be limited.

We market and sell DABRA for use in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label. However, one of our strategies in the future is to pursue additional vascular indications for DABRA and additional dermatological indications for Pharos. Submitting the required applications for additional indications may require substantial additional funding beyond the net proceeds of this offering. We cannot assure you that we will be able to successfully obtain approval for any of these additional product indications through the application process.

Even if we obtain FDA clearance or approval to market our products for additional indications in the U.S., we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop our products for additional indications, our commercial opportunity will be limited, which would have a material adverse effect on our business, financial condition, and results of operations.

We may experience development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

Additionally, since all of our products are manufactured at our facility in Carlsbad, any contamination of the controlled environment, equipment malfunction, or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources.

If our manufacturing activities are adversely impacted, or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition, and results of operations.

If we make acquisitions or divestitures, we could encounter difficulties that harm our business.

To date, the growth of our business has been organic, and we have no experience in acquiring other businesses, products or technologies. We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes. If we use our common stock to acquire companies, products or technologies, our stockholders may experience substantial dilution.

Technological change may adversely affect sales of our products and may cause our products to become obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could adversely affect sales of our products. Our products could be rendered obsolete because of future innovations by our competitors or others in the treatment of vascular diseases and dermatological diseases, which would have a material adverse effect on our business, financial condition, and results of operations.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

Many medical device industry companies are consolidating to create new companies with greater market power. For example, Spectranetics was acquired by Philips in August 2017. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices that incorporate components produced by us. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease and our

earnings, financial condition, or cash flows would suffer, which would have a material adverse effect on our business, financial condition, and results of operations.

Litigation and other legal proceedings may adversely affect our business.

From time to time we are involved in and may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action, and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

We must indemnify officers and directors, including, in certain circumstances, former employees and directors, against all losses, including expenses, incurred by them in legal proceedings and advance their reasonable legal defense expenses, unless certain conditions apply. A prolonged uninsured expense and indemnification obligation could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.

In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations.

For our sales and operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, U.K. Bribery Act, and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third parties, fail to comply with the FCPA and other anti-corruption and anti-bribery laws.

We leverage various third parties to sell our products and conduct our business abroad, including to government owned universities and hospitals. We, our distributors and channel partners, and our other third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses or sales to government owned or controlled health care facilities, universities, institutes, clinics, etc.) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, contractors, third parties, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations.

A variety of risks associated with marketing our products internationally could materially adversely affect our business.

In addition to selling our products in the U.S., we sell Pharos and DABRA outside of the U.S. We are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing reimbursement regimes in foreign countries, including price controls;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition, and results of operations.

We face additional credit and compliance risks related to our international sales using foreign distributors.

We partner with distributors for DABRA and Pharos in select geographies outside of the U.S. Specifically, in 2017 we sold to distributors located in the Netherlands, China, Thailand, United Arab Emirates, and Italy. In 2017, approximately 10% of our sales were outside of the U.S. We may not be able to collect all of the funds owed to us by our foreign distributors. Some foreign distributors may experience financial difficulties, including bankruptcy, which may hinder our collection of accounts receivable. Where we extend credit terms to distributors, we periodically review the collectability and creditworthiness when determining the payment terms for such distributors. If our uncollectible accounts exceed our expectations, this could adversely impact our operating results. In addition, failure by our foreign distributors to comply with the Foreign Corrupt Practices Act or similar laws, insurance requirements, or other contract terms could have a negative impact on our business. Failure to manage the risks related to our foreign distributors would have a material adverse effect on our business, financial condition, and results of operations.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive medical devices industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our senior management team. The loss of the services of any of our executive officers and other key employees, and our inability to find suitable replacements could result in delays in product development and harm our business.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our

company, in addition to salary and cash incentives, we have issued stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees, with the exception of the "key man" insurance policy for our Chief Executive Officer, Dean Irwin. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of DABRA and Pharos, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures and user errors, among other malfunctions. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Technological interruptions would impact our business operations would disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition, and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations

We have identified a material weakness in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal

control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction and a decrease in our stock price.

Following our initial public offering, we will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Such report will not be required until our second annual report filed on Form 10-K. We will need to disclose any material weaknesses identified by our management in our internal control over financial reporting. As an "emerging growth company," we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission, or SEC, or other regulatory authorities, which would require additional financial and management resources.

In prior periods we identified certain material weaknesses in our internal controls related to revenue recognition and lack of staffing in the accounting and finance organization. In connection with these prior material weaknesses we implemented remediation measures including training of accounting personnel as well as hiring additional personnel with experience in the ongoing identification, design and implementation of internal control over financial reporting.

In connection with our 2017 audit, as part of the restatement to the 2016 financial statements described in Note 3 to the financial statements, we identified a material weakness in the design of our internal controls related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication of stock option awards which were not validly authorized. While we have designed and implemented, or expect to implement, measures that we believe address this material weakness, we continue to develop our internal controls, processes and reporting systems by, among other things, hiring qualified personnel with expertise to perform specific functions, including our Chief Financial Officer, the engagement of third party legal counsel to assist in the administration of capital stock transactions, and designing and implementing improved processes and internal controls, including ongoing senior management review and board of directors oversight. We expect to continue to build a more experienced administrative organization with expertise to perform specific functions and to design and implement improved processes and internal controls. We have incurred significant costs to remediate these weaknesses, primarily personnel costs, external consulting and legal fees, system implementation costs, and related indirect costs including the use of facilities and technology, and we expect to incur additional costs to remediate these weaknesses. We may not be successful in implementing these remediation efforts or in developing other internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Further, we will not be able to fully assess whether the steps we are taking will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional errors that result in material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in

business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations.

We could be subject to claims based on defects with respect to certain corporate transactions that were not authorized in accordance with applicable law.

We have determined that due to the material weakness in our internal controls related to the administration of capital stock transactions, there have been defects with respect to certain corporate transactions, including (i) stock issuances that were not or may not have been properly approved by our board of directors and/or adequately documented, (ii) a reverse stock split for which we failed to file the amendment to our articles of incorporation, and (iii) the communication of option awards that were not validly authorized by our board of directors as a result of non-existent or defective board approvals, in each case in accordance with applicable law.

To remediate these defects, we have taken a number of actions. We have ratified the defective stock issuances; obtained agreements from holders of the vast majority of our common stock which include a confirmation of the securities each stockholder holds, a release of potential claims with respect to issuance of securities to such stockholders, and a surrender specifically of any claims to the equity of the Delaware corporation except for the shares of the Delaware corporation that such stockholder has received in the reincorporation merger pursuant to the merger agreement; confirmed with the vast majority of the applicable stockholders that the appropriate number of shares of common stock outstanding immediately prior to the time of the intended reverse stock split were contributed to the capital of the Company effective as of the intended time of, and to give effect to, the intended reverse stock split; and have approved compensation to and obtained releases from our impacted employees and other service providers to resolve potential claims, if any, related to the communicated grants of option awards and to promote retention and align their interests with the long-term interests of our stockholders. While we have attempted to narrow potential future claims by taking certain remedial corporate actions, the scope of liability with respect to such defects is uncertain and we cannot assure that these actions will entirely remediate these defects or that we will not receive claims in the future from other persons asserting rights to shares of our capital stock or to stock options or other equity. To the extent any such claims are successful, they could have a material adverse effect on our business, financial condition and results of operations.

Under certain authority, common law ratification by our board of directors of prior stock issuances may have caused such issuances to be valid stock issuances by us at the time of the respective issuances. However, there is uncertainty under applicable law as to whether such common law ratification may be effective under all circumstances. There can be no assurance that stockholders will not assert claims that a defective corporate act or putative stock issuance ratified by us is void or voidable due to the identified failure of proper authorization by our board of directors, as well as other claims related thereto, and, if

asserted, that any such claims will not be successful. If such ratification is deemed not to be effective, then the issuances of certain shares of our stock and other attempted corporate actions would be invalid and we could have liability to grantees of our common stock, which may have a material adverse effect on our business and results of operations.

We have also confirmed that the vast majority of the applicable stockholders as of the time of the intended reverse stock split contributed a number of shares of common stock sufficient to give effect to the recapitalization intended by the reverse stock split. However, a holder of our common stock could argue that this process does not represent an adequate remedy for a potential failure to properly implement the reverse stock split. If the contribution of shares to the capital of the Company was not effective, then we could have liability to certain holders of our common stock, which may have a material adverse effect on our business and results of operations.

Additionally, we may have potential liability to certain of our employees, directors, consultants, and other service providers for communicated grants of option awards that were not authorized in compliance with applicable law. With respect to the communicated grants of option awards that were not validly authorized, we approved compensation and obtained a release of potential claims from such persons. We approved compensation to our impacted employees, directors, consultants, and other service providers to mitigate potential claims related to the communicated grants of option awards, if any. However, an impacted individual could argue that such compensation is not an adequate remedy for prior invalid option awards and, if a court were to impose a greater remedy, our financial exposure could be greater and have a material adverse effect on our business and results of operations. The foregoing could also result in tax withholding, employment taxes or other tax liabilities, including penalties and interest, all of which could have a material adverse effect on our business, financial condition and results of operations.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

At June 30, 2018, we had 75 full-time employees. As our sales and marketing strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and, accordingly, may not achieve our research, sales and marketing goals, which would have a material adverse effect on our business, financial condition, and results of operations.

We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA and Federal Trade Commission. For example, promotional communications and endorsements on social media that, among other things, promote our products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label uses"), do not contain a fair balance of information about risks associated with using our products, make comparative or other claims about our products that are not supported by sufficient evidence, and/or do not contain required disclosures could result in an enforcement actions against us. In addition, adverse events, product complaints, off-label usage by physicians, unapproved marketing or other unintended messages posted on social media could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. Further, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill, which would have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Regulatory Approval and our Industry

Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA, EMA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time consuming, complex and uncertain. FDA and EMA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacture (including suppliers) and testing;
- pre-clinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Our current products are subject to extensive regulation by the FDA and non-U.S. regulatory agencies. Further, all of our potential products and improvements of our current products will be subject to extensive

regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials, and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The FDA can also refuse to clear or approve pending applications. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition, and results of operations.

Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.

Medical devices regulated by the FDA are subject to "general controls" which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMPs under the Quality System Regulations, or QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to premarket approval, or PMA. None of our current products are Class III devices, but future products could be, which would subject them to the PMA process.

Many medical devices, such as medical lasers, are also regulated by the FDA as "electronic products." In general, manufacturers and marketers of "electronic products" are subject to certain FDA regulatory requirements intended to ensure the radiological safety of the products. These requirements include, but are not limited to, filing certain reports with the FDA about the products and defects/safety issues related to the products as well as complying with radiological performance standards.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. Such reviews and investigations may result in the civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations.

Product clearances and approvals can often be denied or significantly delayed.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data.

The PMA process typically is more costly, lengthy and stringent than the 510(k) process. Unlike a 510(k) review which determines "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the U.S. and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements or additional 510(k) premarket clearances to market modifications to our existing products. The FDA requires device manufacturers to make and document a determination of whether a modification requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not approve our current or future PMA applications or supplements or clear our 510(k) applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Although we have obtained regulatory clearance for our products in the U.S. and certain non-U.S. jurisdictions, they will remain subject to extensive regulatory scrutiny.

Although our products have obtained regulatory clearance in the U.S. and certain non-U.S. jurisdictions, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of

safety, effectiveness, and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable non-U.S. regulatory authorities.

Our manufacturing facility is required to comply with extensive requirements imposed by the FDA, EMA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to the QSR or similar regulations set by foreign regulatory authorities. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510(k) application. Accordingly, we continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted or to the conditions of approval, or contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. However, many physicians use our products for off-label purposes and are allowed to do so. For certain changes to a cleared product, including certain changes to product labeling, the holder of a cleared 510(k) application may be required to submit a new application and obtain clearance.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- subject our facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication, or correspondence;
- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- impose civil or criminal penalties;
- suspend or withdraw regulatory clearances or approvals;
- refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
- seize or detain products; or
- require a product recall.

In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition, and results of operations.

Our products may be subject to recalls after receiving FDA, EMA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA, EMA and similar foreign governmental authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions, or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business. The EMA may also order us to reimburse parties affected by the recall of our products.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA, EMA, or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to Pharos and DABRA that we have received rose to a level required to be reported to the FDA. In response, we informed the FDA that we have modified our complaint review procedures and are in the process of retrospectively evaluating whether product complaints received within the last two years require reporting to the FDA. We intend to complete this retrospective evaluation and submit any required Medical Device Reports, or MDRs, by September 30, 2018. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA, EMA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with the FDA's Quality System Regulation or any applicable state equivalent, our operations could be interrupted and our potential product sales and operating results could suffer.

We are required to comply with the FDA's QSR, which delineates the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. Our facilities have been inspected by the FDA and other regulatory authorities, and we

anticipate that we and certain of our third-party component suppliers will be subject to additional future inspections. If our facilities are found to be in non-compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, FDA could take legal or regulatory enforcement actions against us and/or our products, including but not limited to the cessation of sales or the recall of distributed products, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. We are also subject to periodic inspections by the FDA, other governmental regulatory agencies, as well as certain third-party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations, or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend, prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and/or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product.

Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in the products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

If any of our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, or MDR regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. The most frequent complication reported to us as a result of post-market surveillance is clinically non-significant vessel perforation. If we fail to report these events required to be reported to the FDA within the required

timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require our time and capital, distract management from operating our business, and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed. The ACA has made significant changes to the way healthcare is financed by both federal and state governments and private insurers, and has directly impacted the medical device industry. Among other provisions that may affect our business, including provisions that are meant to contain healthcare costs, improve quality and/or expand access, the ACA implemented, with limited exceptions, a deductible excise tax of 2.3% on sales of medical devices by entities, including us, which manufacture or import certain medical devices offered for sale in the U.S., including many of our products. The tax was to become effective January 1, 2013, but is currently suspended until January 1, 2020. Revenue from many of our products will be subject to that excise tax.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share. Congress may consider additional legislation to repeal or repeal and replace all or certain elements of the ACA, including the medical device excise tax. We continue to evaluate the impact of the ACA and its possible repeal or replacement on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could have a material adverse effect on our business, financial condition, and results of operations.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business.

Our products are purchased principally by catheterization laboratories, which typically bill various third-party payors, including governmental programs, such as Medicare and Medicaid, private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our customers to obtain reimbursement for procedures that are performed using our products from government and private third-party payors is critical to our success. The availability of coverage and reimbursement for procedures performed using our products affects which products customers purchase and the prices they are willing to pay to us.

Reimbursement varies based on country, geographical location and third-party payor and can significantly influence the acceptance of new products and services. Third-party payors may view some procedures performed using our products as experimental and may not provide coverage. Third-party payors may not cover and reimburse our customers for certain procedures performed using our products in whole or in part in the future, or payment rates may not be adequate, or both. Further, coverage and reimbursement by third-party payors to our customers is also related to billing codes to describe procedures performed using our products. Hospitals and physicians use several billing codes to bill for such procedures. Third-party payors may not continue to recognize the CPT codes available for use by our customers.

Reimbursement rates are unpredictable, and we cannot project how our business may be affected by future legislative and regulatory developments. Future legislation or regulation, or changing payment methodologies, may have a material adverse effect on our business, financial condition, and results of operations, and reimbursement may not be adequate for all customers. From time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. Because the cost of our products generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our products. For example, in July 2013, the CMS proposed reimbursement changes that would have decreased reimbursement for procedures in an outpatient based facility. Although CMS chose not to implement those changes in 2013, we cannot assure you that CMS will not take similar actions in the future.

After we develop new products or seek to market our products for new approved or cleared indications, we may find limited demand for the product unless government and private third-party payors provide adequate coverage and reimbursement to our customers. Even with reimbursement approval and coverage by government and private payors, providers submitting reimbursement claims may face delay in payment if there is confusion by providers regarding the appropriate codes to use in seeking reimbursement. Such delays may create an unfavorable impression within the marketplace regarding the level of reimbursement or coverage available for our products.

Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the U.S., there have been and we expect there will continue to be legislative and regulatory proposals to change the healthcare system, such as the potential repeal of the ACA, some of which could significantly affect our business. It is uncertain what impact the current U.S. presidential administration will have on health care spending including a campaign promise to repeal the ACA. If enacted and implemented, any measures to restrict health care spending could result in decreased revenue from our products and decreased potential returns from our research and development initiatives. Other legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures performed using our products or denies coverage for those procedures could have a material adverse effect on our business, financial condition, and results of operations.

Modifications to our products may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing our products until clearances are obtained.

Modifications to our products may require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA will review and can disagree with a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We may make modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions.

Our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services,

as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of ethics and conduct that will become effective upon the completion of this offering, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations.

Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our on our business, financial condition, and results of operations. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations, which could have a material adverse effect on our business, financial condition, and results of operations.

Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation of our cleared devices and any future cleared or approved devices. Our current and future arrangements with providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our cleared devices.

Restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or

indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity for purposes of HIPAA, and we believe that we generally do not conduct our business in a manner that would cause us to be a business associate under HIPAA;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require medical device manufacturers to report information related to payments and other transfers

of value to physicians and other healthcare providers or marketing expenditures. In addition, we may be subject to state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occurs, it could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our existing products and any products we may develop, and our technology may be adversely affected.

As with other medical device companies, our ability to maintain and solidify a proprietary position for our products will depend upon our success in obtaining effective patent claims that cover such products, their manufacturing processes and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, we may not be able to obtain issued claims covering DABRA and Pharos, as well as other technologies that are important to our business, which are sufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to DABRA and Pharos could have a material adverse effect on our business, financial condition, and results of operations.

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside

scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, and the like, although we are unaware of any such defects that we believe are of material importance. If we or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, if any patents are issued in the future, they may not provide us with any competitive advantages, or may be successfully challenged by third parties. Agreement terms that address non-competition are difficult to enforce in many jurisdictions and may not be enforceable in any particular case. To the extent that our intellectual property and other proprietary rights are not adequately protected, third parties might gain access to our proprietary information, develop and market products or services similar to ours, or use trademarks similar to ours, each of which could materially harm our business. Existing United States federal and state intellectual property laws offer only limited protection. Moreover, the laws of other countries in which we now, or may in the future, conduct operations or contract for services may afford little or no effective protection of our intellectual property. The failure to adequately protect our intellectual property and other proprietary rights could materially harm our business.

The strength of patent rights involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own may fail to result in issued patents in the United States or foreign countries with claims that cover our products or services. Even if patents do successfully issue from the patent applications that we own, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products and services. Furthermore, even if they are unchallenged, our patents may not adequately protect our products and services, provide exclusivity for our products and services, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products and services is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products and services.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years

after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our products and services that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and products would be adversely affected.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our products or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether DABRA and Pharos will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims

being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of DABRA and Pharos. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us, which would have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the U.S. over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, and results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the U.S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our products or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Issued patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our patents before administrative bodies in the U.S. or abroad, even

outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our products, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect our proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants, and other third parties, and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our patents, trade secrets or other intellectual property. If we

fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

We may become involved in intellectual property litigation either due to claims by others that we are infringing their intellectual property rights or due to our own assertions that others are infringing upon our intellectual property rights.

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patent infringement and intellectual property rights. Our competitors hold a significant number of patents relating to medical laser technology. From time to time, we may commence litigation to enforce our intellectual property rights. An adverse decision in these actions or in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively impact our business, financial condition and results of operations.

Monitoring unauthorized use of our intellectual property is difficult and costly. Unauthorized use of our intellectual property may have occurred or may occur in the future. Although we have taken steps to minimize the risk of this occurring, any such failure to identify unauthorized use and otherwise adequately protect our intellectual property would adversely affect our business. Moreover, if we are required to commence litigation, whether as a plaintiff or defendant, not only will this be time-consuming, but we will also be forced to incur significant costs and divert our attention and efforts of our employees, which could, in turn, result in lower revenue and higher expenses.

We cannot provide assurance that our products or methods do not infringe the patents or other intellectual property rights of third parties. Additionally, if our business is successful, the possibility may increase that others will assert infringement claims against us.

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of a patent litigation action is often uncertain. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for medical lasers and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. In certain situations, we may determine that it is in our best interests or their best interests to voluntarily challenge a party's products or patents in litigation or other proceedings, including patent interferences or re-examinations. As a result, we may become involved in unwanted litigation that could be costly, result in diversion of management's attention, require us to pay damages and force us to discontinue selling our products.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and

proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. We cannot be certain that we will successfully defend against allegations of infringement of patents and intellectual property rights of others. In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the other party's patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the other party's patents or violate the terms of a license to which we are a party, we could be required to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all, and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid violating or infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of our products.

The medical devices industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and any potential future collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any licensee to alter our development or commercial strategies, obtain licenses, or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Third parties may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our products. In this case, the holders of such patents may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we

may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

For example, in December of 2017, we were contacted by a third party suggesting that we should consider licensing three U.S. patents directed to the treatment of vitiligo, U.S. Pat. No. 6,979,327 ("'327 patent"), U.S. Pat. No. 7,261,729 ("'729 patent"), and U.S. Pat. No. 8,387,621 ("'621 patent"). In addition, we were also previously contacted in 2006 by the same third party suggesting that we should consider licensing the '327 patent as well as the then pending application that became the '729 patent. We believe that we will be meritorious if a claim of infringement of the '327 patent, the '729 patent, or the '621 patent is asserted against us in a legal proceeding by this or any other third party. However, although we believe that we do not infringe the claims of the '327 patent, the '729 patent, or the '621 patent, nor do we believe that we need a license to the '327 patent, the '729 patent, or the '621 patent in order to freely commercialize our products, there is a possibility that a suit claiming infringement of the '327 patent, the '729 patent, or the '621 patent will be brought against us, and we cannot assure that a court or an administrative agency will agree with our assessment with regard to non-infringement of the '327 patent, the '729 patent, or the '621 patent. If it was necessary to obtain a license to the '327 patent, the '729 patent, or the '621 patent and a license was not available on commercially reasonable terms or available at all, that could affect our ability to commercialize our products and materially and adversely affect our business.

If a third party commences a patent infringement action against us it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing products. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our products, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because they may have greater financial resources. Patent litigation and other proceedings may also consume significant management time. Uncertainties resulting from the initiation or continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and scientific advisors are currently or were previously employed at universities or healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we have been and may in the future become subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. For example, in 2018, we received letters from a competitor concerning one of their former employees who is currently working for us. The letters allege, among other things, that the employee is in violation of the employee's continuing obligations to the employee's prior employer. While we dispute the validity of the claims and would vigorously defend against them and assert appropriate defenses, litigation may be necessary to defend against these claims. If we fail in defending any such claims, it could have a material adverse effect on our business, financial condition, and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs to us and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may

be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of the patents that we may own or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Reliance on Third Parties

We depend on third-party suppliers for key components and sub-assemblies used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate components and sub-assemblies could harm our business.

We may encounter unforeseen situations that would result in delays or shortfalls in manufacturing. Key components and sub-assemblies of DABRA and Pharos are currently provided by a limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies. For example, we rely on a limited number of suppliers for the Thyratron used to manufacture our lasers. If we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our costs, result in manufacturing delays, and cause delays in the delivery of our products. We may also experience a delay in completing validation and verification testing or sterility audits for controlled-environment rooms at our facility.

We also depend on limited source suppliers for some of our product components and sub-assemblies, and if any of those suppliers are unable or unwilling to produce these components or sub-assemblies or supply them in the quantities that we need, and at acceptable prices, we would experience manufacturing delays and may not be able to deliver our products on a timely or cost-effective basis to our customers, or at all, which could reduce our product sales, increase our costs, and harm our business. While we believe that we could obtain replacement components from alternative suppliers, we may be unable to do so. Losing any of these suppliers could cause a disruption in our production. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. Establishing additional or replacement suppliers for these materials may take significant time, as certain of these suppliers must be approved by regulatory authorities, which could disrupt our production. As a result, we could experience significant delays in manufacturing and delivering our products to customers. We cannot assure you we can continue obtaining required materials, components, and sub-assemblies that are in short supply within the time frames we require at an affordable cost, if at all. If we cannot secure on a timely basis sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then manufacturing our products may be disrupted, which could increase our costs, prevent or impair our development or commercialization efforts, and have a material adverse effect on our business, financial condition, and results of operations.

We and our component suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we must register with the FDA and non-U.S. regulatory agencies, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our component suppliers comply or can continue to comply with all regulatory requirements. A failure by us or one of our component suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, with a component supplier, until a new supplier has been identified and evaluated. Our or any of our component supplier’s failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we will be able to locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

In the European Union, we must maintain certain International Organization for Standardization, or ISO, certifications to sell our products and must undergo periodic inspections by notified bodies, including the British Standards Institution, to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, it could have a material adverse effect on our business, financial condition, and results of operations.

We may form or seek strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits or costs of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our sales and marketing efforts with respect to our products and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our products. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our products could delay the commercialization of our products in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Risks Related to This Offering and Ownership of Our Common Stock

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future products, which will change from time to time;
- the cost of manufacturing our current and any future products, which may vary depending on FDA and EMA guidelines and requirements, the quantity of production and the terms of our agreements with suppliers;
- the degree and rate of market acceptance for DABRA and Pharos, including the ability of our customers to receive adequate reimbursement for procedures performed using our products;
- expenditures that we will or may incur to acquire or develop additional products and technologies;
- competition from existing and potential future products that compete with our products, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the level of demand for our current and future products, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products, and existing and potential future products that compete with our products;
- our ability to commercialize additional products, if approved, inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing, or other arrangements;
- our ability to adequately support future growth;

- potential unforeseen business disruptions that increase our costs or expenses;
- changes in FDA regulations and comparable foreign regulations;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, after the closing of this offering, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

From time to time, we may also enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend in part on any potential future license and collaboration agreements and sales of our products. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

The price of our stock may be volatile, and you could lose all or part of your investment. Further, we do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering there has been no public market for shares of our common stock. Although we have applied to have our common stock listed on the New York Stock Exchange, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "*Risk factors*" section and elsewhere in this prospectus, these factors include:

- our failure to increase the sales of our products, specifically DABRA;

- the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers;
- unanticipated serious safety concerns related to the use of our products;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our target markets;
- actual or anticipated variations in quarterly operating results;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including stockholder litigation or litigation related to intellectual property;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;

- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

We do not intend to pay dividends on our common stock so any returns will be limited to increases, if any, in our stock's value.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2017, we had net operating loss, or NOL, carryforwards of approximately $7.2 million for federal income tax purposes, and $7.0 million for state income tax purposes. These federal and state NOL carryforwards begin expiring in 2029. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, including this offering, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the Tax Cuts and Jobs Act of 2017, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely and the deductibility of such federal NOLs is limited.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted,

changed, modified or applied adversely to us. For example, on December 22, 2017, President Trump signed tax legislation into law, commonly referred to as the Tax Cuts and Jobs Act of 2017, that contains many significant changes to the U.S. tax laws, the consequences of which have not yet been fully determined. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses contained in the Tax Cuts and Jobs Act of 2017 or other tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items could have a material adverse effect on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax legislation. The impact of this tax legislation on holders of our common stock is also uncertain and could be adverse. We urge our stockholders and investors to consult with our legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately 62% of the outstanding shares of our common stock as of August 23, 2018, and, upon the closing of this offering, that same group will hold approximately % of our outstanding shares of common stock (assuming no exercise of the underwriters' option to purchase additional shares). In addition, as of August 23, 2018, our officers and directors held (i) options to purchase an aggregate of 1,221,000 shares of our common stock at exercise prices of $28.94 per share; and (ii) 858,926 restricted stock units, which would give our officers and directors ownership of approximately % of our outstanding common stock following this offering if such awards are fully vested and are exercised in full (assuming no exercise of the underwriters' option to purchase additional shares). Therefore, even after this offering, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders, which could have a material adverse effect on our business, financial condition, and results of operations.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the New York Stock Exchange to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than anticipated or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. Further, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since our inception, but will own only approximately % of the shares of common stock outstanding after giving effect to this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering. To the extent outstanding options are exercised and outstanding restricted stock units vest, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see "*Dilution*."

Future sales and issuances of a substantial number of shares of our common stock or rights to purchase common stock by our stockholders in the public market could result in additional dilution of the percentage ownership of our stockholders and cause our stock price to fall.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on 8,204,251 shares of common stock outstanding at June 30, 2018, upon the closing of this offering we will have outstanding a total of shares of common stock, assuming no exercise of outstanding options or vesting of outstanding restricted stock units after June 30, 2018. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. The underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

The lock-up agreements pertaining to this offering will expire after 180 days from the date of this prospectus. Subject to certain limitations, approximately shares will become eligible for sale upon expiration of the lock-ups in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, Rule 144 and Rule 701 under the Securities Act, and our insider trading policy. Shares issued or issuable upon the exercise of options vested as of the expiration of the lock-up period will be eligible for sale at that time, as well as shares to be issued upon settlement of outstanding restricted stock units that vest following the completion of this offering. Moreover, pursuant to our 2018 Plan, our Board is authorized to grant equity incentive awards representing up to an aggregate of shares of our common stock to our employees, directors and consultants. The 2018 Plan includes an annual increase in the number of shares available for future grant each year pursuant to the "evergreen" provision of our 2018 Plan. Additionally, pursuant to our ESPP a total of shares are available for sale under our ESPP. The ESPP also includes an annual increase in the number of shares available for sale under our ESPP each year pursuant to the "evergreen" provision of our ESPP. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline.

Further, we expect that significant additional capital may be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock, including shares of common stock sold in this offering.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "*Use of proceeds*," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering for the expansion of our direct sales force and marketing of our products, to support clinical studies for new products and product enhancements including for expanded indications, and to support other research and development activities, working capital, and general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our current management and may adversely affect the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon completion of this offering contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- our board of directors will be divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) or a majority vote of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 $^{2}/_{3}$% of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the issuance of preferred stock and management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt;
- the ability of our board of directors, by majority vote, to amend our amended and restated bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our amended and restated bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, because we are now incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a

court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

SPECIAL NOTES REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the section captioned "*Prospectus summary*," "*Risk factors*," "*Management's discussion and analysis of financial condition and results of operations*," "*Business*," and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these terms.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our plans to obtain funding for our operations, including funding necessary to develop, manufacture and commercialize our products;
- the size and growth of the markets for our products;
- the rate and degree of market acceptance of our products;
- our ability to seek and obtain approvals for new indications for our products;
- our commercialization, marketing, and manufacturing capabilities and strategy;
- our ability to compete with companies currently producing alternative treatment methods;
- our expectations regarding the ease of administration associated with our products;
- pricing and reimbursement for procedures performed using our products;
- our plans to research, develop and commercialize our products and any other approved product;
- our ability to establish the potential immunotherapeutic effects of DABRA with a study or registry;
- the cost, timing and outcomes of any potential litigation involving our products;
- our expectation that our capital resources and the proceeds raised in this offering will be sufficient to fund our operations for our operations for at least the next 12 months;
- regulatory developments in the U.S. and in non-U.S. countries;
- the performance of third parties in connection with the development of our products, including third-party suppliers;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our ability to retain key scientific or management personnel;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology;
- the terms and conditions of licenses granted to us and our ability to license additional intellectual property related to our products, as appropriate;

- our expectations regarding our ability to obtain and maintain intellectual property protection for our products;
- potential claims related to our intellectual property;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our ability to develop innovative new products;
- our financial performance; and
- our anticipated use of the net proceeds from this offering.

In addition, you should refer to the "*Risk factors*" section of this prospectus for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus forms a part with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our general expectations and market position, market opportunity, and market size, is based on information from various third-party industry and research sources, on assumptions that we have made based on that data and other similar sources, and on our knowledge of the markets for our services. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

In addition, industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section captioned "*Risk factors*" and elsewhere in this prospectus. These and other factors could cause our actual results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of common stock in this offering will be approximately $ million at an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds will be approximately $ million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) our net proceeds by $ million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $ million, assuming the assumed initial public offering price stays the same.

We intend to use the net proceeds of this offering as follows:

- approximately $ million for the expansion of our direct sales force and marketing of our products;
- approximately $ million to support clinical studies for new products and product enhancements including for expanded indications; and
- the balance of the proceeds may be used to support other research and development activities, working capital, and general corporate purposes.

We may also use a portion of the net proceeds of this offering for acquisitions to bolster our product offerings. We have not entered into any agreements or commitments with respect to any specific acquisitions and have no understandings or agreements with respect to any such acquisition or investment at this time.

Due to the uncertainties inherent in the product development and commercialization process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. The amount and timing of our actual expenditures will depend upon numerous factors. As a result, our management will have broad discretion over the use of the net proceeds from this offering.

We are undertaking this offering in order to access the public capital markets and to increase our liquidity. At June 30, 2018, we had cash and cash equivalents of $9.8 million. Based on our current plans, we believe that our existing cash and cash equivalents and the net proceeds raised from this offering will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Pending use of the proceeds as described above, we intend to invest the proceeds in a variety of capital preservation investments, including interest-bearing, investment-grade instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions, the terms of any future credit agreements and other factors that our board of directors may deem relevant. See the section entitled "*Material U.S. federal income tax consequences to non-U.S. holders of the ownership and disposition of our common stock*" for a discussion of certain withholding and other tax considerations with respect to dividends paid to non-U.S. holders (as defined therein) of our common stock.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, debt obligations, and capitalization as of June 30, 2018:

- on an actual basis;
- on an as adjusted basis to give effect to the issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of June 30, 2018	
	Actual	As Adjusted[1]
	(in thousands, except share and per share data)	
Cash and cash equivalents	$ 9,769	$
Capitalization:		
Equipment financing	42	
Stockholders' equity:		
Preferred stock, $0.0001 par value; no shares authorized, actual; 10,000,000 shares authorized, as adjusted; no shares issued or outstanding, actual and as adjusted		
Common stock, $0.0001 par value: 25,000,000 shares authorized, actual; 300,000,000 shares authorized, as adjusted; 8,204,251 shares issued and outstanding, actual; shares issued and outstanding, as adjusted	1	—
Additional paid-in capital	50,254	
Accumulated deficit	(40,477)	
Total stockholders' equity	9,778	
Total capitalization	$ 9,820	$

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing as adjusted information is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and the related notes appearing elsewhere in this prospectus and the "*Selected financial data*" and "*Management's discussion and analysis of financial condition and results of operations*" sections of this prospectus.

The foregoing discussion and table is based on 8,204,251 shares of our common stock outstanding as of June 30, 2018 and excludes:

- 1,898,000 shares of common stock issuable upon exercise of options outstanding as of June 30, 2018 that were issued at an exercise price of $28.94 per share under our Compensation Plan;
- 1,340,301 shares of common stock issuable upon the vesting and settlement of restricted stock units outstanding as of June 30, 2018 that were issued under our Compensation Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of:
  - 61,699 shares of common stock reserved for future issuance under our Compensation Plan as of June 30, 2018, which shares will be added to the shares to be reserved under our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for future issuance under our 2018 Plan, which will become effective upon the completion of this offering;
  - shares of common stock reserved for future issuance under our ESPP, which will become effective upon the completion of this offering; and
  - any shares that become available under our 2018 Plan and ESPP, pursuant to provisions that automatically increase the reserves under such plans each year.

DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of our common stock in this initial public offering and the as adjusted net tangible book value per share of our common stock immediately after completion of this offering.

Our historical net tangible book value as of June 30, 2018 was approximately $9.8 million, or $0.60 per share of common stock. Our historical net tangible book value is the amount of our total tangible assets less our total liabilities. Historical net tangible book value per share is our historical net tangible book deficit divided by the number of shares of common stock outstanding as of June 30, 2018.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value (deficit) at June 30, 2018 would have been $ million, or $ per share of common stock. This amount represents an immediate increase in as adjusted net tangible book value (deficit) of $ per share to existing stockholders and an immediate dilution in as adjusted net tangible book value (deficit) of $ per share to new investors.

The following table illustrates this dilution:

Assumed initial public offering price per share		$
Historical net tangible book value per share as of June 30, 2018	$0.60	
Increase (decrease) in as adjusted net tangible book value per share attributable to this offering		
As adjusted net tangible book value per share after giving effect to this offering		
Dilution in as adjusted net tangible book value (deficit) per share to investors purchasing common stock in this offering		$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) our as adjusted net tangible book deficit per share to new investors by $, and would increase (decrease) dilution per share to new investors in this offering by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. In addition, to the extent any outstanding options to purchase common stock are exercised or any outstanding restricted stock units vest, new investors would experience further dilution. If the underwriters exercise their option to purchase additional shares in full, the as adjusted net tangible book value per share of our common stock after giving effect to this offering would be approximately $ per share, and the dilution in as adjusted net tangible book value per share to investors in this offering would be approximately $ per share of common stock.

The following table summarizes, on an as adjusted basis as of June 30, 2018, the total number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid to us by existing stockholders and by new investors purchasing shares of common stock in this offering at the initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					
Total		100%	$	100%	

Except as otherwise indicated, the above discussion and tables assumes no exercise by the underwriters of their option to purchase up to additional shares from us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) each of the total consideration paid by new investors and total consideration paid by all stockholders by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) each of the total consideration paid by new investors and total consideration paid by all stockholders by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. In addition, to the extent any outstanding options to purchase common stock are exercised or any outstanding restricted stock units have vested, new investors will experience further dilution.

If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding after this offering.

The foregoing discussion and tables are based on 8,204,251 shares of our common stock outstanding as of June 30, 2018, and excludes:

- 1,898,000 shares of common stock issuable upon exercise of options outstanding as of June 30, 2018, that were issued at an exercise price of $28.94 per share under our Compensation Plan;
- 1,340,301 shares of common stock issuable upon the vesting and settlement of restricted stock units outstanding as of June 30, 2018 that were issued under our Compensation Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of:
  - 61,699 shares of common stock reserved for future issuance under our Compensation Plan as of June 30, 2018, which shares will be added to the shares to be reserved under our 2018 Plan, which will become effective upon the completion of this offering;

- shares of common stock reserved for future issuance under our 2018 Plan, which will become effective upon the completion of this offering;
- shares of common stock reserved for future issuance under our ESPP, which will become effective upon the completion of this offering; and
- any shares that become available for future issuance under our 2018 Plan and ESPP, pursuant to provisions that automatically increase the reserves under such plans each year.

SELECTED FINANCIAL DATA

The following tables summarize our selected financial data for the periods and as of the dates indicated. We have derived our selected statements of operations data for the years ended December 31, 2016 and 2017, and our selected balance sheet data as of December 31, 2016 and 2017, from our audited financial statements and related notes included elsewhere in this prospectus. We have derived the statements of operations data for the six months ended June 30, 2017 and 2018 and the balance sheet data as of June 30, 2018 from our unaudited interim financial statements and related notes included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect, in the opinion of management, all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the unaudited interim financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and the results for the six months ended June 30, 2018 are not necessarily indicative of results to be expected for the full year or any other period. You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the section captioned "*Management's discussion and analysis of financial condition and results of operations.*"

	Years Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
	(in thousands, except per share data)			
Net revenue	$ 5,976	$ 5,870	$ 2,643	$ 2,205
Cost of revenue	3,138	4,165	1,813	1,726
Gross profit	2,838	1,705	830	479
Operating expenses				
Selling, general and administrative	5,321	14,947	10,028	10,254
Research and development	1,715	4,518	3,746	1,308
Total operating expenses	7,036	19,465	13,774	11,562
Operating loss	(4,198)	(17,760)	(12,944)	(11,083)
Other expense				
Interest expense	3	4	2	2
Total other expense	3	4	2	2
Loss before income tax expense	(4,201)	(17,764)	(12,946)	(11,085)
Income tax expense	1	1	1	3
Net loss	(4,202)	(17,765)	(12,947)	(11,088)
Basic and diluted net loss per share	$ (0.60)	$ (2.35)	$ (1.73)	$ (1.38)
Basic and diluted weighted average common shares outstanding	6,951	7,545	7,464	8,020

	As of December 31, 2016	As of December 31, 2017	As of June 30, 2018
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 3,921	$ 8,237	$ 9,769
Working capital[1]	2,598	7,409	6,109
Total assets	5,842	11,269	16,605
Equipment financing	107	63	42
Accumulated deficit	(11,624)	(29,389)	(40,477)
Total stockholders' (deficit) equity	(380)	(7,615)	9,778

(1) We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Special note regarding forward-looking statements" and "Risk factors" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of the DABRA laser system and disposable catheter, together referred to as DABRA, in the United States. Following the temporary placement period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements or DABRA laser placement acknowledgements with each customer, which we refer to collectively as Usage Agreements. As of June 30, 2018, we had a U.S. installed base of 31 DABRA laser systems, eight of which have signed Usage Agreements with us, and the remainder of which are temporarily placed for use in demonstrations, trials, or training. DABRA is cleared by the U.S. Food and Drug Administration, or FDA, as a tool for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease, which includes peripheral artery disease, or PAD, which commonly occurs in the legs. We intend to pursue additional uses for DABRA, including seeking regulatory clearance for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other venous and arterial occlusions, or blockages in the veins or arteries. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA is our minimally-invasive excimer laser and disposable catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging. Recent analysis suggests that 17.6 million people in the U.S. suffer from PAD. However, only

20-30% of PAD patients are actively being treated. We anticipate revenue from this recently commercialized business segment to grow over the near term. Our sales strategy includes either selling DABRA with a transfer in title or placing it in high-volume practices for a nominal monthly fee while we retain title. We sell extended warranties for our lasers that have been purchased. Each vascular procedure requires the one-time use of our proprietary catheters which we expect to be the primary source of revenue for the vascular segment. Therefore, under both the sale and monthly fee options, we anticipate recurring revenue in catheter sales for each laser in operation. We currently use our internal sales force to target the U.S. market and we utilize distributors outside the U.S. The current retail price of the DABRA laser is approximately $70,000 and of a DABRA catheter is $1,200.

Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. We have also received clearance to market Pharos from the European Medicines Agency, or EMA, China Food and Drug Administration, or CFDA, and South Korea Ministry of Drug Safety, or KFDA in the applicable jurisdictions. Pharos was commercialized in 2004 and we have shipped over 1,000 systems to customers globally. Pharos is in use in nearly every U.S. state and in over 20 markets including several non-U.S. countries. While we have entered into monthly fee arrangements, our primary strategy is to sell Pharos. We recognize additional recurring revenue from the sale of extended warranties for Pharos. We do not anticipate significant organic revenue growth in the near term from this mature product line. The current retail price of Pharos is approximately $70,000.

We incurred net losses of $4.2 million, $17.8 million, and $11.1 million for the years ended December 31, 2016 and 2017 and the six months ended June 30, 2018, respectively, and had an accumulated deficit of $40.5 million as of June 30, 2018. As of June 30, 2018, we had available cash and cash equivalents of approximately $9.8 million and had current liabilities of approximately $5.9 million and long-term liabilities of approximately $0.9 million. As of June 30, 2018, we had no preferred stock outstanding and no indebtedness through commercial loans, other than the equipment financings of $42,000. Since inception, we have financed our operations primarily through sales of our products and services and, to a lesser extent, private placements of our common stock and debt financing arrangements. We expect to continue to incur net losses for the near term as we commercialize our products in the U.S., including building our sales and marketing organization and expanding our manufacturing facilities, continuing research and development efforts, and seeking regulatory clearance for new products and product enhancements, including new indications, both in the U.S. and in select non-U.S. markets. We will need additional funding to pay expenses relating to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, financial condition, and results of operations.

Components of our Results of Operations

Net revenue

Product sales consist of the sale of DABRA and Pharos, the sale of catheters for use in the DABRA laser and the sale of consumables and replacement parts.

Services and other revenues consists primarily of sales of extended warranties which is recognized over the contract period and billable services, including repair activity, which is recognized when the service is provided. It also includes income from the rental of our lasers.

We currently use our internal sales force to target the U.S. market, and we utilize distributors outside the U.S. in markets where we have received regulatory approval. We will continue to seek regulatory approvals for our products in additional strategic markets.

Cost of revenue and gross margin

Cost of revenue for product sales consists primarily of costs of components for use in our products, the materials and labor that are used to produce our products, and the manufacturing overhead that directly support production.

Cost of revenue for services and other includes the cost of maintaining and serving the warranties on our products.

We expect cost of revenue to increase to the extent our total revenue grows.

We calculate gross margin as gross profit divided by total net revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of direct materials, discounting practices, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to increase over the long term as our production volume increases and certain costs remain fixed. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

Research and development, or R&D, expenses consist of applicable personnel, consulting, materials and clinical trial expenses. R&D expenses include:

- certain employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;
- cost of outside consultants who assist with technology development, regulatory affairs, clinical affairs and quality assurance;
- cost of clinical studies to support new products and product enhancements, including expanded indications; and
- supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. In the future, we expect R&D expenses to increase as we continue to develop new products, enhance existing products and technologies and perform activities related to obtaining additional regulatory approval. However, we expect R&D expenses as a percentage of total revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, benefits, travel expense, sales commissions and stock-based compensation expense. Other SG&A expenses include promotional activities, marketing, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses, allocated facilities-related expenses and shipping and handling costs. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing DABRA in both domestic and international markets. We also expect increased costs due to the additional legal, accounting, insurance

and other expenses associated with becoming a public company. As a result, we expect SG&A expenses to increase as a percentage of total net revenue in future periods.

Results of Operations

Comparison of the Six Months Ended June 30, 2017 and 2018

The following table shows our results of operations for the six months ended June 30, 2017 and 2018 (in thousands):

	Six months ended June 30,		Change	
	2017	2018	$	%
Statements of operations data:				
Net revenue				
Product sales	$ 1,301	$ 710	$ (591)	(45%)
Service and other	1,342	1,495	153	11%
Total net revenue	2,643	2,205	(438)	(17%)
Cost of revenue				
Product	1,174	989	(185)	(16%)
Service and other	639	737	98	15%
Total cost of revenue	1,813	1,726	(87)	(5%)
Gross profit	830	479	(351)	(42%)
Operating expenses:				
Selling, general and administrative	10,028	10,254	226	2%
Research and development	3,746	1,308	(2,438)	(65%)
Total operating expenses	13,774	11,562	(2,212)	(16%)
Operating loss	(12,944)	(11,083)	1,861	(14%)
Interest expense	2	2	—	0%
Loss before income taxes	(12,946)	(11,085)	1,861	(14%)
Income tax expense	1	3	2	200%
Net loss	$(12,947)	$(11,088)	$ 1,859	(14%)

Comparison of the Six Months Ended June 30, 2017 and 2018—By reportable segments

We organize our business into two operating segments based on the product specialties: the vascular segment and the dermatology segment. In deciding how to allocate resources and assess performance, we regularly evaluate the net revenue and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to us and not specific to a particular segment; therefore, these amounts are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 11 to the interim condensed financial statements appearing elsewhere in this prospectus.

Net revenue

The following table shows our net revenue from our two segments for the six months ended June 30, 2017 and 2018 (in thousands):

	Six months ended June 30,		Change	
	2017	2018	$	%
Vascular	$ 25	184	$ 159	624%
Dermatology	2,618	2,021	(597)	(23%)
Total net revenue	$ 2,643	$ 2,205	$ (438)	(17%)

Vascular

Net revenue was $25,000 and $0.2 million for the six months ended June 30, 2017 and 2018, respectively. The $0.2 million increase was primarily due increased laser and catheter sales following the FDA clearance of our DABRA system in May 2017 and the commencement of our 12-month commercial launch period in June 2017.

Dermatology

Net revenue was $2.6 million and $2.0 million for six months ended June 30, 2017 and 2018, respectively. The decrease of approximately $0.6 million was due primarily to a decrease of $0.8 million in direct unit product sales as a result of us devoting more of our sales resources in 2018 to commercializing the DABRA laser aggregated in our vascular segment, partially offset by an increase of $0.2 million in income from service contracts on our lasers. We anticipate hiring additional sales resources in the dermatology segment devoted to addressing direct unit product sales.

Cost of revenue

The following table shows our cost of revenue from our two segments for the six months ended June 30, 2017 and 2018 (in thousands):

	Six months ended June 30,		Change	
	2017	2018	$	%
Vascular	$ 7	$ 471	$ 464	*
Dermatology	1,806	1,255	(551)	(30%)
Total cost of revenues	$ 1,813	$ 1,726	$ (87)	(5%)

* Not applicable

Vascular

Cost of revenue was $7,000 and $0.5 million for the six months ended June 30, 2017 and 2018, respectively. The $0.5 million increase was primarily due increased labor, material and overhead costs to support the increased sales of our vascular products.

Dermatology

Cost of revenue was $1.8 million and $1.3 million for the six months ended June 30, 2017 and 2018, respectively. The decrease of $0.6 million was primarily due to a $0.8 million decrease in labor, materials and overhead due to the reduced number of product shipments, partially offset by an increase in service costs and depreciation of $0.2 million due to an increase in the number of leased machines under service agreements.

Gross profit (loss)

The following table shows our gross profit (loss) from our two segments for the six months ended June 30, 2017 and 2018 (in thousands):

	Six months ended June 30,		Change	
	2017	2018	$	%
Vascular	$ 18	$ (287)	$(305)	*
Dermatology	812	766	(46)	(6%)
Total gross profit	$ 830	$ 479	$(351)	(42%)

* Not applicable

Vascular

Gross profit was $18,000 for the six months ended June 30, 2017 and gross loss was $0.3 million for the six months ended June 30, 2018. The $0.3 million change was primarily due to increased costs for labor, material and overhead which exceeded our revenue in the first six months of 2018 due to us staffing ahead of customer adoption and us providing evaluation catheters during this phase of product launch. We expect our gross loss to improve as our customers exhaust their evaluation supplies and purchase production catheters and as our growing sales force and marketing efforts establish a larger customer base.

Dermatology

Gross profit was $0.8 million for both the six months ended June 30, 2017 and 2018. The decrease of $0.6 million in revenue was offset by a $0.6 million decrease in cost of revenues.

Comparison of the Six Months Ended June 30, 2017 and 2018—General

Selling, general and administrative expenses. SG&A expenses were $10.0 million and $10.3 million for the six months ended June 30, 2017 and 2018, respectively. The $0.2 million increase was primarily related to an increase of $1.4 million in personnel costs due to expanding our sales force and hiring administrative staff as we prepare to operate as a public company, an increase of $0.9 million in legal and consulting fees as we prepare to operate as a public company, an increase of $0.3 million in travel and trade shows, $0.2 million in increased facility costs due to our expansion to a larger facility, $0.1 million increase in provision for doubtful accounts and an increase of $0.4 million in various other administrative costs, partially offset by a $3.2 million decrease in stock-based compensation expense.

Research and development expenses. R&D expenses were $3.7 million and $1.3 million for the six months ended June 30, 2017 and 2018, respectively. The $2.4 million decrease was primarily due to a decrease of $2.2 million in stock-based compensation expense and $0.2 million less personnel and resources devoted to catheter research in 2018 as a result of the completion of our initial commercial product development in 2017.

Comparison of the Years Ended December 31, 2016 and 2017

The following table shows our results of operations for the years ended December 31, 2016, and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Statements of operations data:				
Net revenue				
Product sales	$ 3,817	$ 3,067	$ (750)	(20%)
Service and other	2,159	2,803	644	30%
Total net revenue	5,976	5,870	(106)	(2%)
Cost of revenue				
Product	2,289	2,854	565	25%
Service and other	849	1,311	462	54%
Total cost of revenue	3,138	4,165	1,027	33%
Gross profit	2,838	1,705	(1,133)	(40%)
Operating expenses:				
Selling, general and administrative	5,321	14,947	9,626	181%
Research and development	1,715	4,518	2,803	163%
Total operating expenses	7,036	19,465	12,429	177%
Operating loss	(4,198)	(17,760)	(13,562)	323%
Interest expense	3	4	1	33%
Loss before income taxes	(4,201)	(17,764)	(13,563)	323%
Income tax expense	1	1	—	—
Net loss	$(4,202)	$(17,765)	$(13,563)	323%

Comparison of years ended December 31, 2016 and 2017—By reportable segments

We organize our business into two operating segments based on the product specialties: the vascular segment and the dermatology segment. In deciding how to allocate resources and assess performance, we regularly evaluate the net revenue and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to us and not specific to a particular segment; therefore, these amounts are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 14 to the interim condensed financial statements appearing elsewhere in this prospectus.

Net revenue

The following table shows our net revenue from our two segments for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Vascular	$ —	$ 259	$ 259	*
Dermatology	5,976	5,611	(365)	(6%)
Total net revenue	$5,976	$5,870	$(106)	(2%)

* Not applicable

Vascular

DABRA was introduced to the market in 2017 resulting in net revenue of $0.3 million for the year ended December 31, 2017, predominantly from the sale of catheters.

Dermatology

Net revenue was $6.0 million and $5.6 million for the years ended December 31, 2016 and 2017, respectively. The decrease of approximately $0.4 million was due primarily to a decrease of $1.0 million in direct unit product sales as a result of us devoting a portion of our sales resources in 2017 to commercializing the DABRA laser, aggregated in our vascular segment, partially offset by an increase of $0.3 million in service contract revenue and $0.3 million in income from the rental of our lasers.

Cost of revenue

The following table shows our cost of revenue from our two segments for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Vascular	$ —	$ 193	$ 193	*
Dermatology	3,138	3,972	834	27%
Total cost of revenues	$3,138	$4,165	$1,027	33%

* Not applicable

Vascular

DABRA was introduced to the market in 2017 resulting in cost of revenue of $0.2 million for the years ended December 31, 2017, predominantly from catheter shipments.

Dermatology

Cost of revenue was $3.1 million and $4.0 million for the years ended December 31, 2016 and 2017, respectively. The increase of $0.9 million was primarily due to a $0.6 million increase in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants, $0.4 million increase in maintenance costs due to the increased number of machines under service contracts partially offset by a decrease in direct and indirect product costs of $0.2 million due to a decrease in the number of direct product sales as a result of us devoting a portion of our sales and production resources in 2017 to commercializing the DABRA laser, aggregated in our vascular segment.

Gross profit

The following table shows our gross profit from our two segments for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,		Change	
	2016	2017	$	%
Vascular	$ —	$ 66	$ 66	*
Dermatology	2,838	1,639	(1,199)	(42%)
Total gross profit	$2,838	$1,705	$(1,133)	(40%)

* Not applicable

Vascular

DABRA was introduced to the market in 2017 resulting in gross profit of $0.1 million for the years ended December 31, 2017, predominantly from catheter shipments.

Dermatology

Gross profit was $2.8 million and $1.6 million for the years ended December 31, 2016 and 2017, respectively. The decrease of $1.2 million was primarily due to a $0.6 million increase in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants, $0.5 million decrease in product sales and by $0.1 million due to increases in the cost of revenue driven by higher maintenance costs for devices under service contracts. Notes 2 and 11 to the financial statements appearing elsewhere in this prospectus more fully describe the accounting treatment for stock-based compensation awards.

Comparison of years ended December 31, 2016 and 2017—General

Selling, general and administrative expenses. SG&A expenses were $5.3 million and $14.9 million for the years ended December 31, 2016 and 2017, respectively. The $9.6 million increase is primarily related to an increase of $7.4 million in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants, $0.8 million related to increased sales personnel costs as a result of increased headcount, $0.5 million in travel and trade shows related to selling and marketing activities, $0.4 million in facility costs due to the addition of leased locations, which included a charge of $0.2 million for abandoning the lease on a facility that was consolidated and $0.5 million in professional fees, freight and various other administrative costs. Notes 2 and 11 to the interim condensed financial statements appearing elsewhere in this prospectus more fully describe the accounting treatment for stock-based compensation awards.

Research and development expenses. R&D expenses were $1.7 million and $4.5 million for the years ended December 31, 2016 and 2017, respectively. The $2.8 million increase is primarily due to an increase of $2.3 million in stock-based compensation due to the increased fair market value of stock-based compensation awards and additional grants and $0.5 million due to increased personnel costs as a result of increased headcount and consulting costs related to technology development of the DABRA laser and catheters. Notes 2 and 11 to the interim condensed financial statements appearing elsewhere in this prospectus more fully describe the accounting treatment for stock-based compensation awards.

EBITDA and Adjusted EBITDA

EBITDA and Adjusted EBITDA are performance measures that provide supplemental information we believe is useful to analysts and investors to evaluate our ongoing results of operations, when considered alongside other GAAP measures. These Non-GAAP Measures exclude the financial impact of items management does not consider in assessing our ongoing operating performance, and thereby facilitate review of our operating performance on a period-to-period basis. Comparability to our results of operations to other companies may be impacted by our stock-based compensation which was classified as a liability and revalued at each reporting period with the change in fair value recorded to compensation expense in the statement of operations.

We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. Some of these limitations are that:

- EBITDA excludes certain recurring, non-cash charges such as deprecation of fixed assets and amortization of acquired intangible assets and, although these are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future; and
- Adjusted EBITDA further excludes stock-based compensation expense, which has been, and will continue to be for the foreseeable future, a significant recurring expense in our business and an important part of our compensation strategy as well as certain non-recurring items which may affect comparability of our core operations such as the loss on abandonment of facility.

In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison.

A reconciliation is for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with U.S. GAAP is included below. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business. We define Adjusted EBITDA as our GAAP net loss as adjusted to exclude depreciation, amortization, interest expense, income tax expense, stock-based compensation and loss on abandonment of facility.

The following is a reconciliation of Net loss to Adjusted EBITDA (in thousands):

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
	(in thousands)			
Statement of Operations Data:				
Net loss	$(4,202)	$(17,765)	$ (12,947)	$ (11,088)
Depreciation and amortization	95	218	86	231
Interest expense	3	4	2	2
Income tax expense	1	1	1	3
EBITDA	(4,103)	(17,542)	(12,858)	(10,852)
Stock-based compensation	2,300	12,706	10,884	5,204
Loss on abandonment of facility	—	212	—	—
Adjusted EBITDA	(1,803)	(4,624)	$ (1,974)	$ (5,648)

For fiscal 2016, Adjusted EBITDA was $(1.8) million compared to $(4.6) million for fiscal 2017. The decrease in Adjusted EBITDA primarily reflects lower gross profit and higher employee and consulting costs due to increased sales personnel and research and development efforts related to DABRA in fiscal 2017 compared to fiscal 2016.

For the six months ended June 30, 2017, Adjusted EBITDA was $(2.0) million compared to $(5.9) million for the six months ended June 30, 2018. The decrease in Adjusted EBITDA primarily reflects lower gross profit and higher personnel costs due to expanding our sales force and hiring

administrative staff as we prepare to operate as a public company in the first half of 2018 compared to the first half of 2017. In the first half of 2018 we also incurred increased facility costs due to our expansion to a larger facility and higher legal and consulting fees as we prepare to operate as a public company compared to the first half of 2017.

Liquidity and Capital Resources

As of June 30, 2018, we had cash and cash equivalents of $9.8 million and an accumulated deficit of $40.5 million. Our primary sources of capital have been from the sale of our products and services and, to a lesser extent, private placements of common stock and debt financing arrangements. Through June 30, 2018, we raised an aggregate of $27.5 million in proceeds from private placements of our common stock.

We believe that cash and cash equivalents as of June 30, 2018 and the proceeds raised in this offering will be sufficient to fund our operations for at least the next 12 months. As we continue to commercialize DABRA, we expect our costs and expenses to increase in the future as we continue the development of a direct sales force, the expansion of our manufacturing facilities, and as we continue to make substantial expenditures on research and development, including the costs of any future clinical studies. Additionally, we expect to incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our DABRA and Pharos products, related consumables, and other products that may be approved in the U.S. and select non-U.S. markets;
- the costs and expenses of expanding our U.S. and international sales and marketing infrastructure and our manufacturing operations;
- the extent to which our excimer lasers are adopted by the physician community;
- the ability of our customers to obtain adequate reimbursement from third party payors for procedures performed using DABRA;
- the degree of success we experience in commercializing our excimer lasers and related consumables;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our products;
- the costs and timing of developing variations of our excimer lasers, and, if necessary, obtaining FDA clearance to market such variations;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

Cash Flows

	Year ended December 31,				Six Months Ended June 30,			
	Actual		Change		Actual		Change	
	2016	2017	$	%	2017	2018	$	%
Net cash (used in) provided by:								
Operating activities	$ (1,886)	$ (5,523)	$ (3,637)	(193%)	$ (2,771)	$ (5,966)	$ (3,195)	(115%)
Investing activities	(210)	(547)	(337)	(160%)	(241)	(251)	(10)	(4%)
Financing activities	5,373	10,386	5,013	93%	28	7,749	7,721	*
Net increase (decrease) in cash and cash equivalents	$ 3,277	$ 4,316	$ 1,039	32%	$ (2,984)	$ 1,532	$ 4,516	151%

* Not applicable

Net cash used in operating activities

During the year ended December 31, 2016, net cash used in operating activities was $1.9 million, consisting primarily of a net loss of $4.2 million and an increase in net operating assets of $0.1 million primarily related to decreases in accounts receivables, accrued expenses and inventories partially offset by increases in accounts payable and deferred revenue. These items were partially offset by non-cash charges of $2.4 million consisting of depreciation, stock-based compensation expense and common stock issued in exchange for services.

During the year ended December 31, 2017, net cash used in operating activities was $5.5 million, consisting primarily of a net loss of $17.8 million and an increase in net operating assets of $0.8 million, primarily related to decreases in accounts receivable, inventory and deferred revenue. These items were partially offset by non-cash charges of $13.1 million, consisting of depreciation, stock-based compensation expense, common stock issued in exchange for services and a loss on disposal of property and equipment.

Net cash used in operating activities was $2.8 million for the six months ended June 30, 2017. The use of cash in operating activities in the six months ended June 30, 2017, was primarily a result of a net loss of $12.9 million partially offset by non-cash charges of $10.9 million of stock-based compensation and $0.1 million of depreciation expense. Adding to the use of cash was $0.7 million payments for inventory and $0.1 million for other net operating assets and liabilities.

Net cash used in operating activities was $6.0 million for the six months ended June 30, 2018. The use of cash in operating activities in the six months ended June 30, 2018, was primarily a result of a net loss of $11.1 million, partially offset by non-cash charges of $5.2 million of stock-based compensation, $0.2 million of depreciation expense and $0.1 million provision of doubtful accounts. Adding to the use of cash was payments of $0.4 million in net operating asset and liabilities.

Net cash used in investing activities

During the year ended December 31, 2016, net cash used in investing activities was $0.2 million consisting primarily of purchases of manufacturing equipment and selling and accounting software.

During the year ended December 31, 2017, net cash used in investing activities was $0.5 million consisting primarily of purchases of manufacturing equipment.

Net cash used in investing activities was $0.2 million for the six months ended June 30, 2017, consisting primarily of purchases of manufacturing equipment.

Net cash used in investing activities was $0.3 million for the six months ended June 30, 2018, consisting primarily of purchases of manufacturing equipment, tenant improvements and vehicles for our sales force.

Net cash provided by financing activities

During the year ended December 31, 2016, net cash provided by financing activities was $5.4 million, consisting primarily of net proceeds of $5.3 million from the issuance of common stock related to a private placement financing and $0.1 million in equipment financing proceeds.

During the year ended December 31, 2017, net cash provided by financing activities was $10.4 million from the issuance of common stock related to a private placement financing.

Net cash provided by financing activities was $28,000 for the six months ended June 30, 2017, and was primarily a result of proceeds of $0.1 million from the issuance of common stock related to a private placement financing, partially offset by $22,000 of payments on our financed equipment.

Net cash provided by financing activities was $7.8 million for the six months ended June 30, 2018, and was primarily a result of proceeds of $7.9 million from the issuance of common stock related to a private placement financing, partially offset by $0.1 million in payments related to our planned initial public offering and $20,000 of payments on our financed equipment.

OFF-BALANCE SHEET ARRANGEMENTS

We do not engage in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, as a part of our ongoing business. Accordingly, we did not have any off-balance sheet arrangements during any of the periods presented.

RELATED PARTY TRANSACTIONS

Information concerning related party transactions is set forth in the section captioned "*Certain relationships and related party transactions.*"

Contractual Obligations

Our principal obligations consist of the operating lease for our facilities. The following table sets out, as of December 31, 2017, our contractual obligations due by period (in thousands):

	Payments due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations[1]	$4,855	$ 517	$1,014	$961	$ 2,363
Equipment Financing	63	44	19	—	—
Total	$4,918	$ 561	$1,033	$961	$ 2,363

(1) Consists of obligations under multi-year, non-cancelable building leases for our facilities in Carlsbad, California. One lease expired in May 2018 and the remaining two leases expire in December 2021 and December 2027.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this prospectus, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue recognition

Product Sales

We recognize revenue from product sales when the following four criteria have been met: (i) the product has been shipped or services have been performed and we have no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of provisions for expected returns and cash discounts.

None of our sales contain right-of-return provisions and we have historically only experienced nominal returns. However, we estimate a provision for expected returns for the catheter sales used in our DABRA laser system. The provision is based on our best estimate of the number of products that will be returned as defective products based on the nature of the consumable. No provision is made for expected returns from other product sales, including the sales of devices, as we do not have a history of returns. If it becomes known that actual return rates deviate from our original estimates, the provision for expected returns will be adjusted accordingly. The provision for expected returns is recorded as a reduction of accounts receivable and product sales.

We also offer certain cash discounts associated with the sales of our products. These discounts are negotiated on a transaction by transaction basis and therefore do not include any estimate at the time of sale. The discounts are recorded as a reduction to accounts receivable and product sales.

For shipment of our products, we take into account the time at which to recognize revenue, generally this is when title and risk of loss is transferred.

Multiple Element Arrangements

We regularly enter into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include an instrument and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

Arrangement consideration is then allocated to those separate units of account based on their relative selling price. When applying the relative selling price method, the selling price for each deliverable is determined using the following hierarchy: (i) vendor-specific objective evidence, or VSOE, of the selling price; (ii) third-party evidence of selling price; or (iii) best estimated selling price. Our records revenue related to these multiple deliverables as products are delivered and services are performed. In order to establish VSOE of selling price, we must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. In cases where there are not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then we utilize best estimated selling price, or BESP.

We determine BESP for an individual element based on our average selling price of that discrete element during the annual period, excluding transactions that are not representative of standalone sales. We regularly review and maintain our BESP and update these estimates at least annually.

Billable Service Arrangements

Revenue from billable services, including repair activity, is recognized when the service is provided.

Extended Warranty Arrangements

Revenues received with respect to extended warranties on products are recognized over the duration of the extended warranty period on a straight-line basis.

Lease Arrangements

We also derive revenue pursuant to product lease agreements. These leases are classified as operating leases in accordance with the relevant accounting guidelines, and the related revenue is recognized on a straight-line basis.

Distributor Transactions

In certain markets, we sell products and provide services to customers through distributors that specialize in medical device products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. These transactions are accounted for in accordance with our revenue recognition policy described herein.

Stock-based compensation expense

We evaluate whether an award should be classified and accounted for as a liability award or equity award for all stock-based compensation awards granted.

Stock-based compensation for liability awards issued to employees and nonemployee service providers is measured based on fair value of the award using the Black Scholes option pricing model. Changes in the fair value of a liability incurred under a share-based payment arrangement that occur during the requisite service period are recognized as compensation cost over that period. The percentage of the fair value that is accrued as compensation cost at the end of each period is equal to the percentage of the requisite service that has been rendered at that date. Any difference between the amount for which a liability award is settled and its fair value at the settlement date is recorded as an adjustment to compensation cost in the period of settlement.

Stock-based compensation expense for equity instruments issued to employees and nonemployee service providers is measured based on estimating the fair value of each stock option on the date of grant using the Black Scholes option pricing model. Equity instruments issued to nonemployees are valued using the

Black Scholes option pricing model and are subject to revaluation as the underlying equity instruments vest.

We recognize stock-based compensation expense as follows:

	Employees	Nonemployees
Service condition only	Straight-line	Re-value through the performance commitment date
Performance criterion is probable of being met:		
Service criterion is complete	Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence	Re-value the award once the performance criterion is considered probable of occurrence and recognize expense for the then fair value of the award
Service criterion is not complete	Straight-line	Straight-line, except the award is re-valued through the performance commitment date
Performance criterion is not probable of being met	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above

As of December 31, 2016 and 2017, all stock-based compensation awards have been classified as liabilities in the financial statements which is revalued at each reporting period with the change in fair value recorded to compensation expense. The fair value of the stock-based compensation liability was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted below:

- *Fair value of our common stock*—Our shares are not traded in any public market. The common stock value as of the date of grant was based on the share price of recent equity issuances, if available. If there were no such recent transactions, our share valuation was estimated using both the income and market approaches, which were weighted 50% each. A discount of 35% was then applied for lack of marketability for our common stock. As of the reporting date for each period presented, the dates at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with new third party investors who were not previous shareholders of Ra Medical.
- *Risk-free interest rate*—The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term.
- *Volatility*—Expected volatility is based on the historical volatilities of certain “guideline” companies.
- *Expected dividend yield*—Expected dividend yield is based on dividends historically paid by us.
- *Expected life*—The expected life is based on the “simplified” method using the average of the term and vesting period.

As described in Note 9 of the unaudited interim condensed financial statements, on June 4, 2018, our board of directors authorized replacement equity awards of stock options and, effective June 8, 2018, restricted stock units, or collectively, the Replacement Awards. The issuance of the Replacement Awards and cancellation of the stock-based compensation awards classified as liabilities was treated as a modification. As of the date of the modification, which resulted in the settlement of the stock-based compensation liability, the fair value of the stock-based compensation liability was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted below:

- *Fair value of our common stock*—The common stock price was estimated utilizing a hybrid method, a combination of the Probability Weighted Expected Return Method, or PWERM, and Option Pricing Model, or OPM. The estimate incorporated a near-term IPO scenario using PWERM weighted at 80%. Other near-term exit events, a long-term stay private case, and dissolution were all considered as non-IPO scenarios using OPM, and were weighted at 20%. The estimate also reflected a 10% and 15% discount for lack of marketability under PWERM and OPM, respectively.
- *Risk*-free interest rate—The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term.
- *Volatility*—Expected volatility is based on the historical volatilities of certain "guideline" companies.
- *Expected dividend yield*—Expected dividend yield is based on dividends historically paid by us.
- *Expected life*—The expected life is based on the "simplified" method using the average of the term and vesting period.

For stock awards after the completion of this offering, our board of directors intends to determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. We have not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 have occurred.

If ownership changes within the meaning of IRC Section 382 have occurred, it could restrict our ability to use NOL carryforwards and research and development tax credits generated since inception. Limitations on our ability to use NOL carryforwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

Internal Control Over Financial Reporting

In connection with our 2017 audit, as part of the restatement to the 2016 financial statements described in Note 3 to the annual financial statements, we identified a material weakness in the design of our internal controls related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication and authorization of stock option awards which were not validly authorized. While we have designed and implemented, or expect to implement, measures that we believe address these control weaknesses, we continue to develop our internal controls, processes and reporting systems by, among other things:

- hiring qualified personnel with expertise to perform specific functions, including our Chief Financial Officer;
- the engagement of third party legal counsel to assist in the administration of capital stock transactions; and
- designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

Jobs Act Accounting Election

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption. See Note 2 to the interim condensed financial statements included elsewhere in this prospectus for a description of relevant new accounting pronouncements.

Quantitative And Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business, including the effects of interest rate changes and foreign currency fluctuations. Information relating to quantitative and qualitative disclosures about these market risks is described below.

Interest Rate Sensitivity

We had cash and cash equivalents of $9.8 million as of June 30, 2018, which came from sales of our products and services and, to a lesser extent, private placements of common stock and debt financing arrangements. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Most of our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. As of June 30, 2018, the effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

BUSINESS

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of the DABRA laser system and disposable catheter, together referred to as DABRA, in the United States. Following the temporary placement period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements or DABRA laser placement acknowledgements with each customer, which we refer to collectively as Usage Agreements. The terms of the Usage Agreements vary by customer, but each Usage Agreement provides for the specific terms of continued use of DABRA, including periodic maintenance fees. As of June 30, 2018, we had a U.S. installed base of 31 DABRA laser systems, eight of which have signed Usage Agreements with us, and the remainder of which are temporarily placed for use in demonstrations, trials, or training. DABRA is cleared by the U.S. Food and Drug Administration, or FDA, as a tool for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease, which includes peripheral artery disease, or PAD, which commonly occurs in the legs. We intend to pursue additional uses for DABRA, including seeking regulatory clearance for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other venous and arterial occlusions, or blockages in the veins or arteries. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA. DABRA (Destruction of Arteriosclerotic Blockages by Laser Radiation Ablation) is our minimally-invasive excimer laser and disposable catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging. Recent analysis suggests that 17.6 million people in the U.S. suffer from PAD. However, only 20-30% of PAD patients are actively being treated.

Current treatments for vascular blockages associated with PAD are largely endovascular and include angioplasty, stenting and atherectomy. Bypass surgery, which was frequently used in the past, is costly and often results in complications, including high levels of post-surgery pain and lengthy hospital stays and recovery times. Endovascular treatments employ catheter-based products for the displacement or removal of plaque. These treatments also have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease. We believe one of the main contributing factors to high restenosis, or the reaccumulation of blockages, rates for PAD patients treated with endovascular

technologies is the amount of vascular injury that occurs during an intervention. Angioplasty balloons, invented in the 1970's, held a great deal of promise, but the trauma due to their inflation often causes the vessel to reocclude either immediately or over time. Stents, invented in the 1980's, were developed to help keep the arteries open. However, stents can also promote reocclusion and are susceptible to fractures. Atherectomy devices, including the excimer laser, invented in the 1990's, were developed to overcome the drawbacks of angioplasty balloons and stents, which push the plaque to the side of the vessel. DABRA was designed to remove the plaque with less trauma in order to improve patient outcomes when compared to other competing devices.

DABRA is a novel technology for use in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease. We believe that our liquid-filled, full aperture ratio catheter allows for a less traumatic endovascular treatment for the removal of vascular blockages and offers significant benefits over competing treatments and therapies. DABRA is easy to use and can cross and debulk, or reduce or remove, a broad range of blockage types without the use of a guidewire. Although DABRA is suitable for use as a monotherapy, or a therapy that uses one type of treatment, it is predominantly used with angioplasty balloons and also can be used adjunct to drug-eluting balloons, stents, and other endovascular treatments. DABRA employs photochemical ablation, or the removal of body tissue by using photons, to remove blockages by breaking the bonds of the obstructing plaque directly. Unlike many treatments for PAD and other vascular diseases that may damage the arterial wall, DABRA quickly photochemically dissolves plaque with minimal vascular trauma. DABRA is minimally invasive and designed to not stretch the arterial walls or penetrate the layers of arterial tissue known as the subintimal space, which can lead to dissection, or a tear in the inner lining of the vessel wall, or perforation, or a hole or a break in the vessel wall, although these events may still occur with DABRA and other competing products. We believe that endovascular treatments using DABRA may be more durable and longer lasting than treatments using other devices because of the reduced mechanical trauma, thermal trauma, and barometric trauma, or trauma due to change in pressure inside the vessel. Independent in vivo and in vitro research studies have demonstrated that 308 nanometer excimer laser light, which is the same wavelength used in DABRA, increases T-cell apoptosis, or cell death, which may produce an immunosuppressive effect. While we have not established the benefits of this potential immunosuppressant effect in the vasculature, or blood vessels such as arteries or veins, we intend to conduct a registry or study to identify any immunotherapeutic benefits.

The safety and effectiveness of the DABRA laser system and disposable DABRA catheter is supported by our pivotal study, a non-randomized, single-arm, prospective, multi-site study conducted to evaluate plaque photoablation using DABRA in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease. The study enrolled 64 patients at four sites with both above-the-knee and below-the-knee lesions. The final study results demonstrated 94% effectiveness in successful crossing of the target lesion based on angiographic analysis, or a medical imaging technique used to visualize the inside of blood vessels, at time of the procedure with 0% reported serious adverse events. In a study conducted by Spectranetics Corporation, or Spectranetics, as part of its 510(k) application for its CLiRpath Excimer Laser Catheter device, which was the predicate device for our 510(k) application, Spectranetics reported a 79% crossing success with its catheter device and a 72% procedure success in a total of 47 cases. Cumulatively, Spectranetics reported that there were 16, or 34%, serious adverse events reported during the six month follow-up period with the most frequently observed event being reintervention, which occurred in six, or 13%, of cases. The endpoints of both studies were at the time of procedure and at 30 days. Although our pivotal study was not head-to-head with the Spectranetics study, and we may not claim superiority of safety or efficacy, we believe that the patient population in our pivotal study that supported our 510(k) application was substantially similar to the patient population in the Spectranetics study.

In May 2017, we received FDA 510(k) clearance to market the DABRA laser system and disposable DABRA catheter in the U.S. for intended use in ablating a channel in occlusive peripheral vascular

disease. In June 2018, we completed our 12 month commercial launch period, which included training, production, and staffing for the marketing of DABRA in the United States. We market DABRA in the U.S. through our direct sales force, comprised of 15 sales representatives as of June 30, 2018, which places lasers in catheterization laboratories that perform high volumes of endovascular procedures, including atherectomy on peripheral arteries. We have plans to increase sales by further expanding this organization. We are initially focused on placing DABRA in outpatient based laboratories, or OBLs, and subsequently we intend to expand into the hospital catheterization laboratory market. Reimbursement claims for DABRA procedures are typically submitted by the provider to Medicare or another third-party payor using established Current Procedural Terminology, or CPT, codes for atherectomy procedures. DABRA was granted CE mark clearance in September 2016, and we sell systems through distributors in select non-U.S. countries.

Pharos. Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. We have also received clearance to market Pharos from the European Medicines Agency, or EMA, China Food and Drug Administration, or CFDA, and South Korea Ministry of Drug Safety, or KFDA, in the applicable jurisdictions. Pharos offers significant benefits to patients. The targeted nature of our treatment allows the operator to spare healthy tissue from exposure to the ultraviolet light making the treatment faster and safer than some other forms of phototherapy, or light therapy. The light induces T-cell apoptosis which we believe may produce an immunosuppressant effect. For instance, Pharos is not contraindicated for children and pregnant women, allowing for their treatment. In addition, we believe excimer laser treatments can put patients into remission from certain diseases. Treatment with Pharos differs from topical treatments, such as steroids and vitamin D derivatives, which may require frequent ongoing application. Treatment with Pharos also differs from pharmaceuticals treatments, which may be associated with systemic side effects.

Psoriasis is a chronic autoimmune disorder that causes cells to build up rapidly and affects the surface of the skin. The National Psoriasis Foundation reports that psoriasis affects approximately 7.5 million people in the U.S., which accounts for over 2% of the domestic population. Vitiligo is an autoimmune condition in which the skin turns white due to the loss of melanocytes, cells that produce the pigment melanin, which gives skin color. Vitiligo affects 1-2% of the population globally. Atopic dermatitis, more commonly known as eczema, is a chronic eczematous skin disease. There are approximately 17.8 million people in the U.S. suffering from atopic dermatitis. Leukoderma is the localized loss of pigment in the skin due to several causes including vitiligo.

Vascular Disease

Vascular disease refers to diseases of the heart and blood vessels located throughout the body. The most common cause of vascular disease is atherosclerosis. Atherosclerosis is a progressive, degenerative condition in which plaque, consisting of lipids, cholesterol, calcium and other substances found in the blood stream, accumulates on the arterial wall. Plaque occurs in several different forms and may be located throughout the arterial system. Plaque varies in composition, with portions that are hard and brittle, referred to as calcified plaque, and other portions that are fatty or fibrous. Endovascular treatments for atherosclerosis are performed in a catheterization laboratory located in an OBL or hospital. These patients are diagnosed by their primary care physician, podiatrist, or other specialist, and then treatment is performed an interventional cardiologist, interventional radiologist, or vascular surgeon.

PAD is atherosclerosis of the extremities, most commonly in the legs. Smoking, genetic predisposition, diabetes, aging, and obesity may significantly increase the risk of developing PAD. Plaque build-up reduces blood-flow to the surrounding tissue, causing claudication, pain or cramping in the leg, the most

common early symptom of PAD. Symptoms may progress to include numbness, tingling or weakness in the legs and, in severe cases, burning or aching pain in the feet or toes.

As PAD progresses, additional symptoms may develop on the legs, including cooling, color changes, or sores that do not heal. If untreated, PAD can lead to critical limb ischemia, or CLI, a condition where there is not enough oxygenated blood being delivered to the limb to keep the tissue alive. As of June 2017, the SAGE Group reported that conservatively 22 to 30 million people suffer from CLI worldwide. If untreated, CLI may result in ulceration, infection, or gangrene in the feet and legs and eventually limb amputation or death.

Market Overview

Recent analysis suggests that 17.6 million people in the U.S. suffer from PAD. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic and many dismiss symptoms as normal signs of aging. Research indicates only 20-30% of PAD patients are actively being treated.

Without treatment, the disease can result in severe complications and lead to amputation. The most common reason for amputation today is PAD, and up to 180,000 amputations are performed annually in the U.S. Despite the relative undertreatment of PAD, the atherectomy devices industry achieved a $1.08 billion market in 2017 and is estimated to grow at CAGR of over 6% from 2018 to 2022. Higher diagnosis and intervention rates resulting from greater physician and patient awareness of PAD, as well as higher prevalence, are helping drive the market opportunity for PAD treatments.

We believe that the following factors are contributing to a growing diagnosed patient population:

- ***Increased Awareness.*** Recent emphasis on PAD education from medical associations, insurance companies and online medical communities, as well as publication in medical journals is increasing public and physician awareness of PAD risk factors, symptoms and treatment options.
- ***Evolving Physician Practice Patterns.*** Given that many patients with CAD also have PAD, we believe that interventional cardiologists and vascular surgeons are increasingly screening patients for both diseases. As a consequence, we believe that physicians are diagnosing more cases of PAD. In addition, we believe that heightened awareness of PAD, its symptoms and treatment options is leading to increased referrals.

Conventional Means of Treatment and Their Limitations

Physicians typically treat patients with mild to moderate PAD through non-invasive management, including exercise and prescription medication, and, if symptoms worsen, may recommend interventional or surgical procedures. Some patients who initially are diagnosed with severe PAD are treated immediately through interventional or surgical procedures.

Non-Invasive Management. For many diagnosed cases of PAD in the U.S., lifestyle changes, including improved diet, regular exercise and smoking cessation, as well as drug treatment are often prescribed. Although these measures can be effective, many people are unable to sustain them. In addition, these measures may reduce the symptoms, but do not treat the underlying causes of the disease. Physicians may also prescribe medications that lower cholesterol and reduce blood pressure. These drug therapies are generally prescribed for the life of the patient and do not treat the obstruction, making them an ineffective treatment for many patients. As a result, many of these patients will ultimately require more aggressive treatments.

Interventional Procedures. When PAD progresses beyond claudication, physicians may advise intervention, often beginning with minimally-invasive procedures. Minimally invasive endovascular treatments include balloon angioplasty, stents, and atherectomy devices. These treatments have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease. We believe that there are over 500,000 annual endovascular procedures for the treatment of PAD in the U.S. Angioplasty and stenting are the most commonly performed minimally-invasive interventional treatments.

- ***Angioplasty.*** In an angioplasty procedure, a long, thin tube, or catheter, with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guide wire that directs the catheter to the affected area. The balloon is then inflated, compressing the plaque and stretching the arterial wall. While angioplasty catheters are relatively easy to use, they stretch the arterial wall, often leading to dissections of, and damage to, the arterial walls. Angioplasty does not remove the plaque, which remains in the artery. In addition, angioplasty is not well suited to treat highly calcified lesions, lesions concentrated on one side of the arterial wall, or lesions that occur at bifurcations, all common manifestations of PAD in the leg. Further, most angioplasty procedures for PAD are performed with the additional use of a stent.
- ***Stenting.*** Stenting is performed in tandem with angioplasty. A stent is a wire-mesh tube that acts as a scaffold inside the artery to keep it open. Stents are currently available in a wide range of varieties. Despite their widespread use, stents may cause injury and inflammation to the arterial wall during placement and continued trauma post-procedure. Stents placed in the legs are subject to forces and compression that may fracture or crush them, leading to reduced blood-flow and further vessel trauma. Once a stent is implanted, it cannot be removed, which may limit future treatment options such as angioplasty, additional stenting, atherectomy and bypass.
- ***Atherectomy.*** Atherectomy is a procedure to remove plaque. There are several types of atherectomy devices, including directional, rotational and laser, each with different mechanisms of action to remove plaque. Atherectomy treatments are frequently used with a stent or balloon. Atherectomy technologies can damage the vessel walls, which may increase the risk of restenosis. For example, cutting devices, such as directional or rotational devices, introduce significant mechanical trauma and other commercial laser devices have a significant thermal component due to the arrangement of the delivery catheter, both causing trauma to the artery.

Surgical Procedures. Most PAD patients are treated endovascularly. Many of these patients, including diabetics, are not candidates for surgical procedures. However, surgery is used when non-invasive management or interventional procedures have failed or if the patient is diagnosed when PAD has progressed to an advanced state.

- ***Bypass Surgery.*** More severe cases of PAD may be treated by surgeons with bypass surgery. The blood-flow is diverted around the occluded area using a synthetic graft or harvested vessel. Bypass surgery is performed by physicians in an operating room with the patient under general anesthesia and requires multi-day hospital stays for healing and rehabilitation. General anesthesia and the potential for surgical infections make this approach less suitable for patients with conditions such as high blood pressure, heart failure, chronic obstructive pulmonary disease or poor kidney function.
- ***Amputation.*** CLI is a serious form of PAD caused by severe lack of blood-flow to the legs. Physicians may recommend full or partial amputation of the leg or foot for patients with CLI. Up to 180,000 amputations occur annually in the U.S. as a result of PAD.

Our Solution

Strengths of Our Approach

DABRA includes a portable excimer laser system combined with proprietary, single-use catheters that together represent a competitive atherectomy solution for the minimally invasive endovascular treatment of blockages in the vasculature. DABRA represents a novel approach to the treatment of a broad range of vascular blockages that is safe and effective, easy to use, and competitively priced. We believe that the principal benefits of DABRA are:

- ***Safety***. DABRA is designed to track the patient's true lumen, or the center of the artery, and not to penetrate between the layers of arterial structure known as the subintimal space. Damage or stretching of the arterial walls, which can lead to dissection or perforation, may be reduced. No serious adverse events were reported in our 2017 pivotal study, which followed 38 subjects for 180 days, or reported in our post-market surveillance for DABRA. In our post-market surveillance, the most frequent complication reported to us has been clinically non-significant vessel perforation.
- ***Efficacy***. Unlike many treatments for PAD that do not remove plaque, DABRA employs photochemical ablation to disintegrate plaque by breaking its chemical bonds, thereby reducing the plaque to the components of its fundamental chemistry without generating potentially harmful particulates. We believe that eliminating plaque while minimizing injury to the arterial wall may minimize the rate of restenosis. We followed 38 subjects from our pivotal study to 180 days thereafter and all of the subjects were determined to be completely free of target lesion revascularization, or the need to retreat the lesion.
- ***Utility***. DABRA enables physicians to remove plaque from long and calcified lesions in arteries located in the lower extremities both above- and below-the-knee. DABRA is able to cross and debulk a wide variety of plaque, removing vascular blockages that other products are unable to cross without the use of a guidewire. For example, in patients with a chronic total occlusion, or CTO, the physician may use DABRA to cross the CTO prior to alternative treatments consisting of balloon angioplasty and possibly stenting.
- ***Ease of Use***. DABRA employs techniques similar to those used in angioplasty, which are familiar to the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the U.S. who are generally trained in endovascular techniques. This significantly increases the number of physicians who are able to perform the procedure compared to surgical alternatives that must be performed by highly-trained vascular surgeons.
- ***Cost and Time Efficient***. We believe that because our single-use DABRA catheters are priced competitively and because we provide the DABRA laser system for a nominal periodic fee without requiring the purchase of capital equipment, DABRA is a cost-effective solution for providers. Providers are also eligible for reimbursement for procedures that are performed using DABRA by using existing Current Procedural Terminology, or CPT, codes. In addition, DABRA's easy setup and fast ablation speed reduce both treatment and fluoroscopy time, or x-ray exposure time, for the patient, physician, and staff, improving the providers' patient throughput. The average lasing time in our pivotal study was approximately two and a half minutes per procedure.
- ***Immunotherapeutic Benefits***. Research performed using 308 nanometer laser energy, the wavelength of Pharos, demonstrated increased T-cell apoptosis, which may produce an immunosuppressant effect. Unlike with Pharos, where we can measure the degree and speed of clearance of disease and quantify the remission time, with DABRA we have not established the benefits of this immunosuppressant effect in the vasculature. We intend to conduct a registry or study to identify any immunotherapeutic benefits.

Our Strategy

Our goal is to become the leading medical device company marketing excimer lasers as tools for the treatment of endovascular diseases. Key elements of our strategy to achieve this goal are:

- ***Driving physician awareness of DABRA***. Our program to educate physicians regarding DABRA's value proposition consists of presentations and exhibits at industry conferences, advertising in medical journals, direct visits, webinars, and calls.
- ***Creating patient awareness of DABRA***. We are establishing marketing and support programs with physicians and patient advocacy organizations to create patient awareness of PAD treatment options in order to generate demand for our products.
- ***Expanding DABRA sales***. We provide physicians with clinical training to drive adoption and utilization of DABRA. We believe that a strong sales team to train physicians on the use and the benefits of DABRA will increase sales. We expect to continue to expand the clinical sales team through 2018 and beyond.
- ***Extending DABRA to additional indications***. We plan to leverage our product technology and research and development expertise to develop DABRA for additional vascular indications, such as CAD and in-stent restenosis.
- ***Expanding commercial opportunities for DABRA internationally***. We received the right to affix the CE mark to DABRA in the third quarter of 2016, permitting DABRA to be marketed and sold in Europe and other CE mark markets. We plan to expand commercial opportunities for DABRA internationally through obtaining additional regulatory approvals and expanding our relationships with international distributors.
- ***Optimizing existing manufacturing capabilities to generate operating leverage***. We design, develop and manufacture DABRA in-house using components and sub-assemblies provided by third-party suppliers. We believe that by controlling the manufacturing and assembly of our products we are able to innovate more quickly, produce higher quality products, and increase our manufacturing scale in a cost-effective manner. We intend to use our design, engineering, and manufacturing capabilities to further improve the efficiency of our manufacturing process and expand our margins.
- ***Expanding our product offerings***. We believe that we will be able to leverage our technology and sales platform to expand our endovascular offerings with ancillary endovascular devices such as angioplasty balloons, guide catheters, and introducers. We intend to achieve this through our internal development efforts and with selective licenses, alliances or acquisitions of complementary products, technologies or businesses.

The DABRA Product

DABRA combines a portable excimer laser console with proprietary, single-use catheters for the minimally invasive endovascular treatment of vascular blockages resulting from lower extremity vascular disease in both above- and below-the-knee lesions. DABRA benefits from our expertise in excimer lasers gained from over a decade developing, manufacturing, testing, marketing, and servicing the Pharos excimer laser for dermatological diseases.

We believe that DABRA is the only endovascular device that crosses chronic total occlusions and removes plaque without a guidewire. The most important aspect of DABRA for the vascular market is the catheter, which conducts energy from the laser to the vascular blockage. The laser energy travels through the catheter and ablates the blockage, reducing it to chemicals that are found naturally in the bloodstream. The catheters are sterilized single-use only and specifically designed for our laser-based systems. The DABRA catheter uses a liquid-filled plastic tubing instead of glass fiber optic construction allowing for the efficient and precise delivery of the laser energy.

The DABRA Laser

The DABRA catheter is a single-use, 5 French gauge catheter that does not use a guidewire to navigate vasculature and which typically stays within the normal area in which blood is flowing or true lumen, even while crossing blockages. It is a full aperture ratio forward cutter, delivering fast ablation of all types of plaque, without the “dead-space” of fiber optic bundle catheters. It produces a high quality lumen while minimizing trauma to the vasculature. The DABRA catheter has a 1.5 millimeter blunt-tip design and a working length of 150 cm that tracks the true lumen, navigating the vascular curves. DABRA catheters have been used with a variety of introducers and 7 French gauge guide catheters. They have been used in both above- and below-the-knee procedures, including axially, femorally, both antigrade and retrograde, from popliteal access and pedal access, both anterior tibial and posterior tibial. DABRA removes plaque by photochemical ablation, limiting the vascular trauma caused by mechanical forces, acoustic or thermal energy, or vapor bubbles, used in competing products.

The DABRA Catheter

The DABRA excimer laser is the power source for DABRA catheters that generates a laser light by a software controlled 308 nm excimer laser source that produces 308 nanometer ultraviolet-B photons that are directed to the catheter through a lens to photochemically ablate vascular blockages, reducing calcium, thrombus, and atheroma into their fundamental chemistry, minimizing downstream debris.

DABRA ablation produces fast treatment times and minimizes fluoroscopy time. The laser is small enough for most catheterization laboratories, weighs approximately 110 pounds, and is easily portable around and between rooms. It is easy-to-use, features a simple and intuitive operator-interface, plugs into a standard 110-volt outlet, and does not require any pumps or fluids.

The DABRA Procedure

During the procedure, the physician inserts the proximal end of the disposable DABRA catheter into the laser console. Using the buttons next to the screen of the console, the physician enters the calibration mode and inserts the catheter into the calibration port of the console to perform the calibration. The physician sets the treatment settings on the touch screen. The physician then inserts the catheter into the support catheter and under

fluoroscope, advances the catheter to the target lesion. The physician uses the footswitch to activate the laser unit and slowly advances the catheter to ablate the target lesion.

Depending upon the type of lesion, DABRA can cross blockages at a rate of up to one centimeter per second. The DABRA procedure is typically performed under local anesthesia in a catheterization laboratory. Procedures performed using DABRA have an approximate two and a half minute total lasing time. A patient treated in an OBL is discharged the same day.

Clinical Studies and Patient Data

Pre-Marketing Studies. We applied and received FDA IDE approval to treat up to 50 adult patients in the U.S. for our pivotal study. It was a non-randomized, single-arm, prospective, and multi-site study that enrolled 64 patients at four sites. The objective of the study was to evaluate plaque photoablation using DABRA in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease in patients with Rutherford categories 3, 4, 5 and 6. The primary efficacy endpoint was the successful crossing of the target lesion based on angiographic analysis at time of the procedure. The safety endpoint was device-related major adverse events at the time of the procedure. It was conducted at four centers including the California Heart and Vascular Center, an OBL in El Centro, California, Centro Medico Excel, a hospital in Tijuana, Mexico, the University of California, San Diego, a major teaching hospital in San Diego, California, and Wesley Medical Center, a hospital in Hattiesburg, Mississippi. As part of the inclusion criteria for the DABRA study, the target blockage must have been refractory to guidewire crossing. The average lasing time in our study was approximately two and a half minutes and the average lesion measured over seven centimeters, which is representative of a typical patient suffering from severe lower extremity vascular disease. The analyses pre- and post-treatment were performed using standard angiographic and ultrasonic tools which are commonly used in commercial catheterization laboratories.

The study was closed to enrollment on May 24, 2017 when we received 510(k) clearance for DABRA and contained data on 64 patients. The final study results demonstrated 94% effectiveness with 0% reported serious adverse events. Furthermore, in our study, 64 lesions crossed were above the knee, or approximately 85%, and 11 lesions crossed were below-the-knee, or approximately 15%. In a study conducted by Spectranetics as part of its 510(k) application for its CLiRpath Excimer Laser Catheter device, which was the predicate device for our 510(k) application, Spectranetics reported a 79% crossing success with its catheter device and a 72% procedure success in a total of 47 cases. Cumulatively, Spectranetics reported that there were 16, or 34%, serious adverse events reported during the six month

follow-up period with the most frequently observed event being reintervention, which occurred in six, or 13%, of cases.

The endpoints of both studies were at the time of procedure and at 30 days. Although our pivotal study was not head-to-head with the Spectranetics study, and we may not claim superiority of safety or efficacy, we believe that the patient population in our pivotal study that supported our 510(k) application was substantially similar to the patient population in the Spectranetics study. The following is a summary of our clinical study for DABRA:

	Patients (64)		Age					
			M		F			
	M	F	Mean	Median	Mean	Median	Patient Successes	# of Serious Adverse Events
Totals:	48	16	71	69	73	77	60	0

Lesion Locations	Number of Lesions
CFA	2
Iliac	1
Proximal SFA	12
Mid SFA	30
Popliteal	14
Peroneal	2
TP Trunk	2
Anterior Tibial	8
Posterior Tibial	1

We followed 38 subjects from our pivotal study to 180 days thereafter and all of the subjects were determined to be completely free of target lesion revascularization, or the need to retreat the lesion.

The Pharos Product

The Pharos Laser

Pharos is a powerful, monochromatic, or single-wavelength, xenon-chlorine, 308 nanometer ultraviolet-B excimer laser used by physicians as a tool to treat chronic skin diseases, including psoriasis, vitiligo, atopic dermatitis, and leukoderma. We launched Pharos in 2004. Pharos does not use heat and does not ablate lesions, and treatments are generally painless. Pharos' proprietary hand piece features an integrated adjustable spot size and aiming beam that accurately targets only the diseased tissue while sparing the healthy skin from exposure. The laser beam is easily contoured to accommodate the shape of the lesion for fast and precisely targeted treatments with constant fluence, or stream of photons crossing a unit area. No templates or attachments are required. Its flat-top, no hot-spot beam profile delivers uniform dosing for optimal results. Pharos is small enough for most treatment rooms, intuitive to use, and uses a standard 110-volt outlet.

The Pharos treatment is generally performed in a dermatology treatment room in an office, clinic or hospital. In most states and countries in which we have received regulatory approval, the treatment can be applied by a nurse or technician. The laser is calibrated, the desired dose is entered, and the hand piece is directed to the patient. The treatment is delivered through a hand piece that has a distance gauge which is placed on the patients' skin and is operated by a foot switch. The hand piece is moved to the appropriate lesion location and the process is repeated until all of the lesions have been dosed.

We believe that the principal benefits of Pharos are:

- ***Wavelength.*** Studies have shown that the action spectrum, or the rate of a physiological activity plotted against wavelength of light, for immunologically modulated skin disorders is centered at about 308 nanometers. Pharos is a 308 nanometer laser, making it ideally suited for use as a tool in the treatment of these disorders.
- ***Energy.*** The energy from excimer lasers has been shown, in both in vivo and in vitro studies, to have almost four times the T-cell apoptosis generation than non-laser sources. Pharos is a pulsed laser capable of producing very high peak powers and we believe that this may produce an immunosuppressive effect.
- ***Collimation.*** Ultraviolet-B light has a very shallow penetration into the skin, typically less than 100 microns. Although the skin tends to scatter the light, collimation, or keeping the light rays parallel, helps prevent reflection and improves the dose delivery. Pharos has a moderately collimated beam and this collimation allows for treatment in intertriginous areas, such as the groin and armpits, and mucosal areas, such as the mouth and ears, without compromising dose.
- ***Targeting.*** Applying the laser energy only to the diseased tissue not only spares the healthy tissue from exposure, but also allows the operator to increase the dose to the affected areas. We believe that Pharos is the only system that has an integrated adjustable spot size offering continuous beam adjustment from a large square to a small circle.
- ***Footprint.*** Dermatological treatment rooms are small and often crowded with other equipment. Pharos has a small footprint and is among the lightest excimer lasers currently marketed, allowing physicians to conserve space and easily move the system.

There are essentially three main types of current treatments for dermatological skin disorders, which each have limitations, as listed below:

- ***Topical therapies.*** These can include corticosteroids, vitamin D3 derivatives, coal tar, anthralin and retinoids, among others, that are sold as a cream, gel, liquid, spray, or ointment. The efficacy of topical agents varies from person to person, and these products are commonly associated with poor compliance or side effects that include irritation, redness, and thinning of the skin.
- ***Phototherapy.*** There are several ultraviolet lamp systems that deliver ultraviolet-A and ultraviolet-B light for the treatment of skin conditions. Broadband ultraviolet therapy can be less desirable than targeted laser machines due to exposure of non-diseased skin and limited ability to deliver high intensity light, requiring more treatment sessions and increasing cancer risk.
- ***Systemic medications including biologicals.*** There are a number of prescription medications available, which are delivered orally or by injection. Generally, these drugs are administered only after both topical treatments and phototherapy have failed, or for people who have severe disease. Some of the side effects include risks of infection or death.

Dermatological Disease

Dermatological disease refers to diseases of the skin caused by imbalance in the physiological condition of the skin. There are over 3,000 different skin conditions and diseases, including psoriasis, vitiligo, and atopic dermatitis. Psoriasis is a chronic autoimmune disorder that causes cells to rapidly accumulate and affects the surface of the skin. The extra skin cells form scales and red patches, or flares, which are itchy and sometimes painful. There is no known cure and multiple rounds of treatments are required to bring the disease under control. Vitiligo is an autoimmune condition causing the skin to turn white due to the

loss of pigment from the melanocytes, cells that produce the pigment melanin, which gives skin color. There is no known cure. However, some medical treatments can reduce the severity of the condition. Atopic dermatitis, a chronic eczematous skin disease, can result in itchy, red, swollen, and cracked skin.

Additional proliferative skin disorders include alopecia areata, dyshidrotic eczema, and cutaneous T-cell lymphoma, or CTCL. Alopecia areata is a condition in which hair is lost from some or all areas of the body. Dyshidrotic eczema is a skin disease characterized by itchy blisters on the palms of the hands and bottoms of the feet. CTCL is a type of cancer of the immune system caused by a mutation of T-cells.

Market Overview

Psoriasis, atopic dermatitis and vitiligo are common skin disorders throughout the world. The National Psoriasis Foundation reports that psoriasis affects approximately 7.5 million people in the U.S., which accounts for over 2% of the domestic population. Globally, this skin condition is estimated to afflict over 125 million people. Direct and indirect healthcare costs related to psoriasis in the U.S. alone are roughly $11.25 billion annually. Lost time from work accounts for an additional $11.2 billion per year, as the majority of psoriasis patients miss an average of 26 days of work a year due to their disease. Currently, 17.8 million people suffer from atopic dermatitis in the U.S., making it one of the most common inflammatory skin diseases. Vitiligo is a pigmentation disorder that affects 1% to 2% of the population globally. Alopecia areata affects about 2% of the population in the U.S., or about six million people. There are approximately 30,000 CTCL sufferers in North America.

Sales and Marketing

We market and sell DABRA and Pharos primarily through our direct sales force in the U.S. As of June 30, 2018, we had a 15-person direct sales force in the U.S. with 12 persons focused on vascular and three persons focused on dermatology. Our sales force is organized by geographic sales territories, and each territory is managed by a sales manager who acts as the primary customer contact. We plan to continue to increase the size of our sales organization to expand our installed unit base and to increase utilization of the DABRA and Pharos. Our initial focus for DABRA is high-volume OBLs. We partner with distributors for DABRA and Pharos in select geographies outside of the U.S.

Our marketing department currently consists of five professionals. Our marketing program focuses on:

- educating physicians regarding the proper use and application of DABRA and Pharos;
- supporting physicians' efforts to enhance referral opportunities;
- improving patient and caregiver awareness of our treatments; and
- facilitating national and international marketing programs.

We use a targeted marketing approach to introduce our products to the medical marketplace. We primarily target our marketing efforts to practitioners through marketing materials, medical conferences and journals. In addition, we host seminars and webinars where industry leaders discuss case studies and treatment techniques using DABRA and Pharos.

Manufacturing

We manufacture our excimer lasers and catheters in our approximately 32,000 square foot facility located in Carlsbad, California. Our vertically integrated facility is ISO 9001 and ISO 13485 certified and is licensed by the state of California to manufacture our sterile single-use catheters in our controlled environments. We specify and source our supplies primarily from U.S.-based manufacturers, contracting with local suppliers to manufacture custom components. We carefully choose our suppliers to ensure that all components meet our quality standards, adhere to all applicable regulations, and meet our supply needs. We inspect, test, and

assemble our products under strict manufacturing processes supported by internal policies and procedures. We perform our own final quality control testing of all products before shipment. In addition to primary suppliers, secondary suppliers have been identified for contingency planning purposes for many key components. We audit our suppliers as required by our quality system and the FDA. We believe that our current manufacturing capacity is sufficient to produce enough lasers and catheters to meet our current expected demand for at least the next 12 months.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our competitors also include pharmaceutical companies that manufacture drugs for the treatment of PAD or other dermatological diseases. Our overall competitive position is dependent upon a number of factors, including product performance and reliability, manufacturing cost, and customer support.

Vascular blockages are currently treated with angioplasty balloons, stents, and atherectomy devices that include excimer laser ablation. Our major competitors for our vascular solutions include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., including Volcano Corporation and Spectranetics Corporation, Becton Dickinson and Company, including products from the C.R. Bard acquisition, and Abbott Laboratories. We believe that DABRA competes favorably with our competitors' products in terms of safety, ease of use, utility and cost.

Dermatological diseases are currently treated with phototherapy, topical therapies, and systemic medications. Our major competitors for our dermatological solutions include The Daavlin Company, National Biological Corp., STRATA Skin Sciences and large pharmaceutical companies producing biologicals. We believe Pharos competes favorably with our competitors' products.

Reimbursement

Our customers do not receive reimbursement for the purchase of our products. However, procedures performed using DABRA and Pharos are reimbursable using existing CPT codes. At this time the Company believes that the existing CPT codes are generally adequate to cover procedures performed using the Company's products, without the need to apply for separate product specific CPT codes. Sales of DABRA and Pharos in the U.S. depend in part on the availability of coverage and adequate reimbursement to our customers for use of our products from third-party payors, such as private health insurers, managed care organizations and government health programs, like Medicare, Medicaid, TRICARE and the Veterans Administration. Medicare's coverage and reimbursement policies are significant to our operations, as a large percentage of DABRA and Pharos procedure patients are Medicare beneficiaries, and private third-party payors often rely upon Medicare coverage and reimbursement policies in setting their own payment policies. However, no uniform coverage and reimbursement policy for services and products exists among third-party payors in the U.S. You should refer to the "*Risk factors*" section of this prospectus for risks related to reimbursement.

Procedures performed using DABRA and Pharos are generally reimbursed using the below CPT codes. The 2018 facility and non-facility reimbursement amounts are included in the table below. The non-facility reimbursement amounts are the payment rates for services performed in the OBL setting. Generally, the reimbursement is higher in the non-facility setting because the physician incurs the practice expense for providing the service.

2018 Medicare National Payment Amounts

DABRA LASER (Endovascular)

CPT Code	Non-Facility Reimbursement Amount	Facility Reimbursement Amount	Procedure
37225	$11,130.36	$636.83	Fem/popl revasc w/ather
37227	$15,061.51	$765.35	Fem/popl revasc stnt & ather
37229	$10,975.92	$742.31	Tib/per revasc w/ather
37231	$13,605.33	$798.11	Tib/per revasc stent & ather
37233	$1,464.46	$345.60	Tib/per revasc w/ather add-on
37235	$4,194.31	$420.48	Tib/per revasc stnt & ather

PHAROS LASER (Dermatology)

CPT Code	Non-Facility Reimbursement Amount	Facility Reimbursement Amount	Procedure
96920	$168.12	$68.76	Laser tx skin < 250 sq cm
96921	$184.32	$77.40	Laser tx skin 250-500 sq cm
96922	$250.92	$124.56	Laser tx skin > 500 sq cm

Market acceptance of the DABRA and Pharos devices is dependent on adequate payment levels from third-party payors to our customers. We receive payment from the provider, facility or other entity that purchases, leases, rents or uses the DABRA or Pharos devices and purchases related supplies. A physician who performs a procedure utilizing either device may be reimbursed separately by third-party payors for their services. Under Medicare, the physician would be reimbursed according to the physician's fee schedule in effect at the time of the procedure.

Reimbursement to facilities and physicians can vary substantially depending on the third-party payors' coverage and reimbursement policies and other factors. For example, the type and geographical location of the facility in which the procedure was performed may impact the level of reimbursement. In addition, the specific use of the product may impact reimbursement. For example, the Pharos treatment of psoriasis is reimbursable by Medicare and nearly all major insurance companies under three CPT codes that differ based on the affected area to be treated. As a result, there is wide variability in reimbursement, and third-party payor's reimbursement policies are subject to change. Further, requests for reimbursement are subject to challenge, reduction or denial by third-party payors.

Research and Development

The major focus of our research and development team is to leverage our existing technology platform for new applications. Future research and development efforts will involve continued enhancements to and cost reductions for DABRA and Pharos. We will also explore the development of other products that can be derived from our core technology platform and intellectual property. Our research and development team works together with our sales force to set development priorities based on communicated customer needs. The feedback received from our customers is reviewed and evaluated for incorporation into new products. Over the last two fiscal years, we have invested over $6.2 million in principal research and development programs ($1.7 million and $4.5 million for the years ended December 31, 2016 and 2017, respectively).

Patents and Proprietary Technology

Patents

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patent, copyright, trademark and trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights. The protection of intellectual property has been and remains a priority for us. As of July 11, 2018, we own three issued patents and continue to pursue patent protection in five different patent families. In the patent family titled "Small Flexible Liquid Core Catheter for Laser Ablation in Body Lumens and Methods for Use," we own one issued U.S. patent, one issued Chinese patent and a pending European patent application which has received a Communication from the European Patent Office under Rule 71(3) indicating an intent to grant the application. A U.S. divisional application has also been filed in this patent family and remains pending. In the patent family titled "Methods and Devices for Treatment of Stenosis of Arteriovenous Fistula Shunts," we own one issued U.S. patent and three divisional applications remain pending in the U.S. A U.S. patent application titled "Laser Ablation Catheters Having Expanded Distal Tip Windows for Efficient Tissue Ablation" is currently pending in addition to a U.S. patent application titled "Catheter Grip Device and Method." A pending U.S. patent application titled "Liquid Filled Ablation Catheter with Overjacket" has been converted to a pending Japanese national stage application with plans to further convert this application into the national stage in the U.S., China and Europe. Our issued U.S. patents expire between 2035 and 2036, subject to payment of required maintenance fees, annuities, and other charges.

Trademarks

We own or have rights to trademarks that we use in connection with the operation of our business. We own or have rights to trademarks for Ra Medical Systems and our logo as well as other marks such as DABRA and Pharos.

Trade Secrets

We also rely upon trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

Government Regulation and Product Approval

United States

In the U.S., medical devices are subject to extensive regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act, or the FDC Act, and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending pre-market approval applications, or PMAs, issuance of warning letters or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class II devices provide intermediate levels of risk. They are subject to general controls, and some Class II devices

must also comply with special controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by FDA before they are marketed.

Generally, establishments that manufacture devices are required to register their establishments with the FDA and provide FDA a list of the devices that they handle at their facilities.

Pre-market Authorization and Notification

While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a pre-market approval, or PMA, application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices; or (iii) authorized the device to be marketed through the de novo process, generally applicable for novel Class I or II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because FDA has not yet called for PMAs for these devices.

510(k) Notification

Product marketing in the U.S. for most Class II and limited Class I devices typically follows a 510(k) pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. A predicate device may be a previously 510-(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications, or a product previously granted de novo authorization. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

There are three types of 510(k)s: traditional; special, for devices that are modified and the modification needs a new 510(k) but the modification does not affect the intended use or alter the fundamental scientific technology of the device; and abbreviated, for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review. The FDA intends to process special 510(k)s within 30 days of receipt, and abbreviated 510(k)s within 90 days of receipt. Though the FDA has a user fee goal to clear a traditional 510(k) within 90 days of receipt, the clearance pathway for traditional 510(k)s can take substantially longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FD&C Act, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDC Act. This provision allows FDA to classify a low- to moderate-risk device not previously classified into Class I or II.

PMA Approval

A product not eligible for 510(k) clearance must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction.

Results from adequate and well-controlled clinical trials are required to establish the safety and effectiveness of a Class III PMA device for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all preclinical, clinical, and other testing, and information relating to the product's marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA.

The PMA approval process is generally more expensive, rigorous, lengthy, and uncertain than the 510(k) premarket notification process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The FDA's review of a PMA application typically takes one to three years, but may last longer. If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a premarket notification. For significant risk devices, the FDA regulations require that human clinical investigations conducted in the U.S. be approved via an investigational device exemption, or IDE, which must become effective before clinical testing may commence. A nonsignificant risk device does not require FDA approval of an IDE. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. If the FDA disapproves the IDE within this 30-day period, the clinical trial proposed in the IDE may not begin.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to granting PMA approval, the FDA typically inspects the records relating to the

conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Clinical trials are typically conducted at geographically diverse clinical trial sites, and are designed to permit FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device. Clinical trials, for significant and nonsignificant risk devices, must be approved by an institutional review board, or IRB – an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Investigational devices may only be distributed for use in an investigation, and must bear a label with the statement: "CAUTION—Investigational device. Limited by Federal law to investigational use."

Postmarket Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act). In addition, we are subject to medical device reporting regulations that require us to report to the FDA, EMA, or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to Pharos and DABRA that we have received rose to a level required to be reported to the FDA. In response, we informed the FDA that we have modified our complaint review procedures and are in the process of retrospectively evaluating whether product complaints received within the last two years require reporting to the FDA. We intend to complete this retrospective evaluation and submit any required Medical Device Reports, or MDRs, by September 30, 2018. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet.

The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products, and if we promote our products beyond their approved indications, we may be subject to enforcement actions or prosecution arising from that off-label promotion. Violations of the FDCA relating to the inappropriate promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

For a PMA or Class II 510(k) or de novo device, the FDA also may require post-marketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, quality-control, manufacture, packaging, and labeling procedures must continue to conform to QSRs after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with QSRs. The FDA may withdraw product approvals or recommend product recalls if a company fails to comply with regulatory requirements. The FDA has the authority to conduct mandatory recalls, but that authority is rarely used.

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

We have received 510(k) premarket clearances from the FDA to market our excimer laser and catheter systems for treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma, and vascular blockages resulting from lower extremity vascular disease. We expect to file additional 510(k) submissions for other diseases including, but not limited to, CAD, alopecia areata, and oral lichen planus in the future.

Radiation Emitting Products

For all radiation emitting devices, additional requirements apply under the Electronic Product Radiation Control Provisions of the FDC Act. Electronic product radiation means (i) any ionizing, or non-ionizing electromagnetic or particulate radiation, or (ii) any sonic, infrasonic, or ultrasonic wave emitted from an electronic product as the result of the operation of an electronic circuit in the product. The additional regulations on these products are intended to protect the public from hazardous or unnecessary radiation exposure emitted by these products. These requirements include compliance with applicable radiation safety performance standards and additional reporting to the FDA. The performance standards for lasers include specific user labeling requirements, radiation limitations, and technological requirements for certain safety features.

Non U.S. Regulatory

We have additional clearances from China, from both the CFDA and State Food and Drug Administration, or sFDA, and Korea, from the KFDA. In addition, we also received CE mark for the Pharos dermatological and DABRA vascular system in the third quarter of 2016, enabling our product launch in Europe. The FDA clearances and the CE mark also allow us to sell these products in other large markets.

Other Healthcare Laws

Our business operations and current and future arrangements with healthcare professionals, consultants, customers and patients, expose us to broadly applicable state and federal fraud and abuse and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- in addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities may conclude that some of our business practices, including our promotional activities and interactions with our customers do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, additional integrity reporting and oversight obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

International Laws

In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

U.S. Healthcare Reform

In the U.S. and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the U.S., in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers. Among the ACA's provisions of importance to our business are the following:

- implementation of a 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, which, due to subsequent legislation will not go into effect until January 1, 2020;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs.

Employees

As of June 30, 2018, we had 75 full-time employees. Our ability to manage growth effectively will require us to continue to implement and improve our management systems, recruit and train new employees and select qualified independent contractors. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Facilities

We entered into a ten year lease agreement for our new corporate headquarters, which includes our manufacturing facility, located at 2070 Las Palmas Drive, Carlsbad, California 92011 on August 17, 2017. This lease term began on January 1, 2018 and will expire on December 31, 2027. This property consists of approximately 32,000 square feet that will allow for anticipated growth for the foreseeable future and for us to maintain our employees under one roof. We are currently operational in this facility.

We have invested in our manufacturing facility, including making upgrades to our controlled environments by increasing the total square footage from approximately 500 square feet to approximately 2,000 square feet. This provides an adequate work area for fabricating sterile, high quality catheters for the DABRA laser systems and high-reliability laser pump chambers to support both the dermatology and the vascular markets. We have further invested in capital equipment and staff, and believe that our current manufacturing capacity will be sufficient to meet the current expected demand for our products for at least the next 12 months. We believe our existing facility is capable of producing 400 lasers per year and 70,000 catheters per year.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business, financial condition, and results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the names, ages, and positions of our executive officers and directors as of August 23, 2018:

Name	Age	Position
Executive Officers		
Dean Irwin	56	Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors
Andrew Jackson[1]	49	Chief Financial Officer and Secretary
Jeffrey Kraws	54	Co-President
Melissa Burstein, M.B.A.	43	Executive Vice President and Director
Directors		
Dean Irwin	56	Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors
Melissa Burstein, M.B.A.	43	Executive Vice President and Director
Richard Heymann[2]	63	Director of Corporate Strategy and Business Development and Director
Martin Burstein, M.B.A.[2]	71	Director
Maurice Buchbinder, M.D.[3]	65	Director
Martin Colombatto[4][5]	60	Director
William R. Enquist, Jr.[3][5][6]	61	Director
Richard Mejia, Jr.[4][5][7]	70	Director
Mark E. Saad[3][4][8]	48	Director

(1) Mr. Jackson joined us as chief financial officer in April 2018 and was appointed as secretary in July 2018. Prior to April 2018, Daniel Sanchez-Linares served as our acting chief financial and principal financial officer.
(2) Mr. Burstein and Mr. Heymann each intend to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement to which this prospectus forms a part.
(3) Member of the nominating and corporate governance committee.
(4) Member of the audit committee.
(5) Member of the compensation committee.
(6) Mr. Enquist joined our board of directors in July 2018.
(7) Mr. Mejia joined our board of directors in July 2018.
(8) Mr. Saad joined our board of directors in July 2018.

Executive Officers

Dean Irwin founded Ra Medical in 2002 and has served as Chief Executive Officer, Chief Technology Officer and Chairman of the Board since September 2002 and as Co-President since May 2018. Prior to forming Ra Medical, Mr. Irwin was Vice President of Research, Development, and Engineering at PhotoMedex, Inc., a manufacturer of excimer lasers, from February 1998 to August 2002. Prior to his tenure at PhotoMedex, Inc., Mr. Irwin provided scientific consulting for Intel Corporation from January of 1999 to August 1999 and was Vice President of Engineering and General Manager at SpatiaLight, Inc., a manufacturer and seller of high-resolution liquid crystal on silicon microdisplays, from June 1993 to February 1998. Mr. Irwin was also a founder and Chief Scientist at DIR Corp., a custom equipment development company, from May 1985 to January 1991. Mr. Irwin has held various engineering positions with Acculase, Inc., a laser development company, (acquired by PhotoMedex), General Atomics, a defense contractor, and Universal Voltronics Corp., a developer of high voltage power supplies. We believe that Mr. Irwin is qualified to serve as a member of our board of directors due to his

senior management roles in multiple companies in the medical devices industry and his deep understanding of our business, operations, and strategy.

Andrew Jackson has served as our Chief Financial Officer since April 2018 and as our Secretary since July 2018. From October 2016 to April 2018 he was Chief Financial Officer for AltheaDx, Inc, a molecular diagnostics company specializing in precision medicine. From March 2014 to March 2016, Mr. Jackson held senior financial positions, including Chief Financial Officer, at Celladon Corporation, a publicly-traded, clinical stage biotechnology company. From April 2013 to March 2014 he held senior financial positions at Sapphire Energy, an industrial biotechnology company. Mr. Jackson received a MSBA in Finance in December 2006 from San Diego State University and a BSB in Accounting in June 1992 from the University of Minnesota. Mr. Jackson is also a certified public accountant (inactive).

Jeffrey J. Kraws has served as our Co-President since May 2018 and served as the President of Ra Medical from August 2016 until May 2018. Since 2003, Mr. Kraws has served as Chief Executive Officer and co-founder of Crystal Research Associates and CRA Advisors. Mr. Kraws is a partner at Grannus Securities Pty Ltd. (an Australian based private equity fund) since November 2015. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also served in the treasury group at Bristol-Myers-Squibb Company. Mr. Kraws serves on the board of directors of Avivagen (TSX:VIV), Saleen Automotive, Inc. (OTC: SLNN), and is Chairman of the Board of Synthetic Biologics (NYSE:SYN). Mr. Kraws holds an MBA from Cornell University and a BS degree from State University of New York, Buffalo.

Melissa Burstein co-founded Ra Medical in September of 2002 and has served as its Executive Vice President, and as a Director since September 2002, Ms. Burstein also served as our Secretary from 2002 until 2018. Prior to co-founding Ra Medical, Ms. Burstein held various sales and marketing positions with Eli Lilly and Co., a pharmaceutical company from September of 2001 to March 2003. Ms. Burstein also previously served as Marketing Intern at the Kellogg Company, a consumer packaged goods company from January 2000 to August 2000 and as an Analyst for Sprint International, a telecommunications company from June 1997 to August 1999. Ms. Burstein holds an MBA specializing in international management from Thunderbird, the American Graduate School of International Management, and a B.S. from Georgetown University. We believe that Ms. Burstein is qualified to serve as a member of our board of directors due to her extensive experience in marketing and sales and her deep understanding of our business, operations and strategy.

Directors

Dean Irwin. Please see the biographical information above in the section entitled "*—Executive Officers*."

Melissa Burstein. Please see the biographical information above in the section entitled "*—Executive Officers*."

Richard Heymann has served as a director of Ra Medical since July 2008 and as an employee in Corporate Strategy and Business Development since January 2016. Mr. Heymann has served as the

President and Chief Executive Officer of Noteworthy Advisors, a real estate, consulting and investment firm since July 2002. Prior to his role at Noteworthy Advisors, Mr. Heymann served as President of Security Financial Bancorp, a real estate, private lender and investment company from 1992 to July 2002. Mr. Heymann attended the University of Wisconsin and holds a B.A. from Idaho State University. We believe that Mr. Heymann is qualified to serve as a member of our board of directors due to his business acumen and his deep understanding of our company and values. Mr. Heymann intends to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of this registration statement to which this prospectus forms a part.

Martin Burstein has served as a director of Ra Medical since October 2003. Mr. Burstein served as the Vice President of Administration from 2004 to 2012 and the Vice President of Human Resources from 1999 to 2004 for Panasonic Disc Manufacturing Corporation of America, an independently operated subsidiary of Panasonic Corporation of America. He also served as Vice President, Human Resources for Sybase, Inc. from 1997 to 1998, and Director of HR Operations for MFS Communications Company from 1995 to 1997. Mr. Burstein holds an MBA from the University of Missouri. We believe that Mr. Burstein is qualified to serve as a member of our board of directors due to his extensive management experience and his deep understanding of our business and strategy. Mr. Burstein intends to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement to which this prospectus forms a part.

Maurice Buchbinder has served as a director of Ra Medical since January 1, 2017. Dr. Buchbinder has served as Interventional Cardiologist for Maurice Buchbinder M.D., C.M., A Professional Corporation, from October 1994 to present. Dr. Buchbinder holds a Bachelor's of Science degree from McGill University in Montreal, Canada, and a Doctor of Medicine, Master of Surgery, from McGill University. He completed his post-graduate education at Stanford University where he specialized in Cardiovascular Medicine. We believe that Dr. Buchbinder is qualified to serve as a member of our board of directors due to his extensive experience in the medical and medical device industries.

Martin Colombatto has served as a director of Ra Medical since January 2017. Mr. Colombatto has served as a Venture and Industry Partner of Seven Peaks Ventures LLP, a venture capital fund based in Bend, OR, since January 2016. From December 2013 to August 2014, Mr. Colombatto served as a director of PLX Technology, Inc., a technology company. Mr. Colombatto has also served as the Chief Executive Officer and President of Staccato Communications, Inc., an Ultra Wideband semiconductor company, from January 2006 to March 2009 and as Executive Chairman of Staccato Communications, Inc., from January 2006 to September 2010. Prior to joining Staccato, Mr. Colombatto served as Vice President and General Manager of the Networking Business unit of Broadcom Corp., a broadband communication semiconductor company, from July 1996 to July 2002. Mr. Colombatto was also previously employed by LSI Logic, an application specific semiconductor company, from August 1987 to July 1996. Mr. Colombatto also previously held engineering positions at Reliance Electric, a production automation and control company, from August 1985 to June 1987 and Texas Instruments, an electronics company, from June 1982 to April 1985. Mr. Colombatto holds a Bachelor's of Science Degree in Electronic Engineering Technology from California State Polytechnic University, Pomona. We believe that Mr. Colombatto is qualified to serve as a member of our board of directors due to his extensive management experience and familiarity with our business and strategy.

William R. Enquist, Jr. has served as a director of Ra Medical since July 2018. Mr. Enquist held various roles at Stryker Corporation, a medical device company, from 1986 to 2014, including Advisor from 2013 to 2014 and President, Global Endoscopy from 1998 to 2013. From 2015 to 2016, Mr. Enquist served as the chairman of the board of directors of EndoChoice Holdings, Inc., a publicly traded medical device company, until its acquisition by Boston Scientific in 2016. From 2014 to 2016, Mr. Enquist served as a member of the board of directors of Firefly Medical Inc., a medical device company. Mr. Enquist currently is chairman of the board of directors of Clinical Innovations and board director

for SpineEx, both medical device companies. Mr. Enquist earned a BBA from the University of San Diego and completed Harvard University's Program for Management Development. We believe that Mr. Enquist is qualified to serve as a member of our board of directors because of his extensive experience as a senior executive officer of other healthcare companies.

Richard Mejia, Jr. has served as a director of Ra Medical since July 2018. Mr. Mejia previously served as a partner in the San Diego office of Ernst & Young LLP, a public accounting firm, from 1988 up until his retirement in 2008, including that from 2001 through 2008 he led the Life Sciences practice. Mr. Mejia currently serves as a member of the board of directors of SkyBell Technologies, Inc., a technology company. From 2014 to 2018 he served on the Board of Stemedica Cell Technologies, Inc., a life science company and from 2008 to 2015, Mr. Mejia served on the board of directors of Dot Hill Systems Corp., a public company which manufacturers software and hardware storage systems. From 2010 to 2012 he served on the board of directors of Sharp Health, a healthcare delivery system. Mr. Mejia holds a B.S. in Accounting from the University of Southern California. We believe that Mr. Mejia is qualified to serve as a director because of his extensive experience in public accounting, financial matters, industry knowledge and serving on boards of directors.

Mark E. Saad has served as a director of Ra Medical since July 2018. Mr. Saad currently serves as Partner and Chief Operating Officer of Alethea Capital Management, LLC, an asset management firm based in San Diego. From August 2014 to February 2017, Mr. Saad served as the Chief Financial Officer of Bird Rock Bio, Inc., a clinical stage biopharmaceutical company focused on developing innovative immuno-inflammatory regulators. Previously, Mr. Saad served as Chief Financial Officer of Cytori Therapeutics, a medical device developer and manufacturer, from 2004 to 2014, where he was responsible for finance and accounting, business development, and other operating functions. Prior to Cytori, he served as Executive Director of UBS Investment Bank, a multinational investment bank and financial services company, where he was the Chief Operating Officer of the Global Healthcare Group. Prior to UBS, Mr. Saad was part of the Health Care Investment Banking Group at Salomon Smith Barney, an investment bank. Mr. Saad has been a member of the board of directors of Axsome Therapeutics, Inc., a clinical-stage biopharmaceutical company, since December 2014. Mr. Saad holds a Bachelor of Arts from Villanova University. We believe that Mr. Saad is qualified to serve as a member of our board of directors due to his financial expertise and leadership experience.

Board Composition and Risk Oversight

Our business and affairs are managed under the direction of our board of directors. The number of directors will be fixed by our board of directors, subject to the terms of our amended and restated
certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering. Our board of directors currently consists of nine directors. Mr. Burstein and Mr. Heymann intend to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement to which this prospectus forms a part. Although we presently have nine directors, as a result of the resignations of Mr. Burstein and Mr. Heymann from our board of directors, our board of directors will be reduced from nine to seven directors, effective upon the effectiveness of the registration statement to which this prospectus forms a part. Five of the directors who will continue to serve on our board of directors following this offering qualify as "independent" under New York Stock Exchange, or NYSE, listing standards, including Martin Colombatto, Maurice Buchbinder, Richard Mejia, Jr., Mark E. Saad, and William R. Enquist, Jr.

Following the completion of this offering, our amended and restated certificate of incorporation and our amended and restated bylaws will provide that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows:

- the Class I directors will be Dean Irwin and Mark E. Saad, and their terms will expire at the annual meeting of stockholders to be held in 2019;
- the Class II directors will be Melissa Burstein, Martin Colombatto and Maurice Buchbinder, and their terms will expire at the annual meeting of stockholders to be held in 2020; and
- the Class III directors will be Richard Mejia, Jr. and William R. Enquist, Jr., and their terms will expire at the annual meeting of stockholders to be held in 2021.

Upon expiration of the term of a class of directors, directors for that class will be elected for three-year terms at the annual meeting of stockholders in the year in which that term expires. Each director's term shall continue until the election and qualification of his or her successor, or his or her earlier death, resignation or removal. Any additional directorships resulting from an increase in the number of authorized directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control. Under Delaware law, our directors may be removed for cause by the affirmative vote of the holders of a majority of our outstanding voting stock. Directors may not be removed by our stockholders without cause. See "*Description of capital stock—anti-takeover effects of Delaware law and our certificate of incorporation and bylaws*" for a discussion of these and other anti-dilution provision found in our amended and restated certificate of incorporation.

Director Independence

Upon the completion of this offering, we anticipate that our common stock will be approved for listing on the NYSE. Under the rules of the NYSE, independent directors must comprise a majority of a listed company's board of directors within a specified period of the completion of its initial public offering. In addition, the rules of the NYSE require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the NYSE, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Martin Colombatto, Maurice Buchbinder, Richard Mejia, Jr., Mark E. Saad, and William R. Enquist, Jr., representing five (5) of our seven (7) directors who will continue to serve following this offering, is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of the NYSE. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section captioned "*—Certain relationships and related party transactions*."

Our co-founders, Dean Irwin, currently serving as our Chief Executive Officer, Co-President, Chief Technology Officer and Chairman of our board of directors, and Melissa Burstein, currently serving as our Executive Vice President and a member of our board of directors, are married. Additionally, Martin Burstein, currently serving as a member of our board of directors, is Ms. Burstein's father and Mr. Irwin's father-in-law. Other than the relationships described above, none of our directors or officers has a family relationship with any other director or officer.

Lead Independent Director

Our board of directors has adopted corporate governance principles that provide that one of our independent directors should serve as our Lead Independent Director at any time when our Chief Executive Officer serves as the Chairman of our board of directors or if the Chairman is not otherwise independent. Because Dean Irwin is our Chairman and is not an "independent" director as defined in the listing standards of the NYSE, our board of directors has appointed Martin Colombatto to serve as our Lead Independent Director. As Lead Independent Director, Mr. Colombatto will preside over periodic meetings of our independent directors, serve as a liaison between our Chairman and our independent directors, and perform such additional duties as our board of directors may otherwise determine and delegate.

Board Committees

In July 2018, our board of directors established, effective upon the effectiveness of this offering, an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will be comprised and will have the responsibilities described below. Each of the below committees will have a written charter approved by our board of directors. Each of the committees will report to our board of directors as such committee deems appropriate and as our board of directors may request. Upon completion of this offering, copies of each charter will be posted on the investor relations section of our website.

Audit Committee

Our audit committee will be comprised of Richard Mejia, Jr., Martin Colombatto, and Mark E. Saad. Mr. Mejia will serve as the chairperson of our audit committee. Our board of directors has determined that each member of our audit committee meets the requirements for independence and financial literacy under the applicable rules and regulations of the SEC and the listing standards of the NYSE. Our board of directors has also determined that Mr. Mejia is an "audit committee financial expert" as defined in the rules of the SEC and has the requisite financial sophistication as defined under the listing standards of the NYSE. The responsibilities of our audit committee will include, among other things:

- selecting and hiring the independent registered public accounting firm to audit our financial statements;
- overseeing the performance of the independent registered public accounting firm and taking those actions as it deems necessary to satisfy itself that the accountants are independent of management;
- reviewing financial statements and discussing with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews, and the reports and certifications regarding internal control over financial reporting and disclosure controls;
- preparing the audit committee report that the SEC requires to be included in our annual proxy statement;
- reviewing the adequacy and effectiveness of our internal controls and disclosure controls and procedures;

- overseeing our policies on risk assessment and risk management;
- reviewing related party transactions; and
- approving or, as required, pre-approving, all audit and all permissible non-audit services and fees to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, which satisfies the applicable rules and regulations of the SEC and the listing standards of the NYSE.

Compensation Committee

Our compensation committee will be comprised of Martin Colombatto, Richard Mejia, Jr., and William R. Enquist, Jr. Mr. Colombatto will serve as the chairperson our compensation committee. Our board of directors has determined that each member of our compensation committee meets the requirements for independence under the applicable rules and regulations of the SEC and listing standards of the NYSE. Each member of the compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. The purpose of our compensation committee will be to oversee our compensation policies, plans and benefit programs and to discharge the responsibilities of our board of directors relating to compensation of our executive officers. The responsibilities of our compensation committee will include, among other things:

- reviewing and approving or recommending to the board for approval compensation of our executive officers;
- reviewing and recommending to the board for approval compensation of directors;
- overseeing our overall compensation philosophy and compensation policies, plans and benefit programs for service providers, including our executive officers;
- reviewing, approving and making recommendations to our board of directors regarding incentive compensation and equity plans; and
- administering our equity compensation plans.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, which satisfies the applicable rules and regulations of the SEC and the listing standards of the NYSE.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will be comprised of Mark E. Saad, Maurice Buchbinder, M.D., and William R. Enquist, Jr. Mr. Saad will serve as the chairperson of our nominating and corporate governance committee. Our board of directors has determined that all members of our nominating and corporate governance committee meet the requirements for independence under the applicable rules and regulations of the SEC and listing standards of the NYSE. The responsibilities of our nominating and corporate governance committee will include, among other things:

- identifying, evaluating and selecting, or making recommendations to our board of directors regarding, nominees for election to our board of directors and its committees;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees; and
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters.

Our nominating and corporate governance committee will operate under a written charter, to be effective prior to the completion of this offering, which satisfies the applicable rules and regulations of the SEC and the listing standards of the NYSE.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

Director Compensation

As of December 31, 2017, none of our non-employee directors held any outstanding equity awards to purchase shares of our common stock. We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees.

The following table presents information concerning each grant of an award made to our non-employee directors under our Compensation Plan subsequent to December 31, 2017:

Name	Principal Position	Grant Date	Shares Subject to Stock Options	Shares Subject to Restricted Stock Units
Martin Burstein	Director	June 4, 2018	42,000(1)	—
		June 4, 2018	150,000(2)	—
		June 8, 2018	—	30,390(3)
		June 8, 2018	—	148,860(4)
Martin Colombatto	Director	June 4, 2018	42,000(1)	—
		June 8, 2018	—	30,390(3)
Maurice Buchbinder	Director	June 4, 2018	42,000(1)	—
		June 8, 2018	—	30,390(3)

(1) One thirty-sixth of the shares subject to the option vest each month over the thirty six months following January 1, 2017, on the same day of the month, subject to the director's continued service. In the event of a Change in Control (as defined in the Compensation Plan), one hundred percent (100%) of the shares subject to the option shall immediately vest.

(2) One-third of the shares subject to the option shall vest on the one year anniversary of the date of grant and one thirty-sixth of the shares subject to the option shall vest monthly thereafter, subject to the director's continued service.

(3) Thirty-three percent (33%) of the restricted stock units shall vest on the 10th day of the third month following the expiration of the Lock-Up Period (as defined in the award agreement), thirty-three percent (33%) of the restricted stock units shall vest on the 15th day of the sixth month following the expiration of the Lock-Up Period, and thirty-four (34%) of the restricted stock units shall vest on the 20th day of the ninth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

(4) Fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the first month following the expiration of the Lock-Up Period (as defined in the award agreement), fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the second month following the expiration of the Lock-Up Period, fifteen percent (15%) of the Restricted Stock Units shall vest on the 15th day of the fourth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 15th day of the fifth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the seventh month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the eighth month following the expiration of the Lock-Up Period, and ten percent (10%) of the restricted stock units shall vest on the 25th day of the tenth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

The following table sets forth information concerning compensation paid or accrued for services rendered to us by members of our board of directors for the year ended December 31, 2017. Mr. Irwin and Ms. Burstein are executive officers and did not receive any additional compensation for their services as directors. Information concerning the compensation earned by Mr. Irwin and Ms. Burstein is set forth in the section captioned "*Executive compensation*." Mr. Heymann is a non-executive employee of the Company, but has been included below. Additionally, the table excludes Richard Mejia, Jr., Mark E. Saad, and William R. Enquist, Jr. who were appointed to our board of directors in 2018.

Name	Fees Earned or Paid in Cash ($)	All Other Compensation ($)	Total ($)
Maurice Buchbinder, M.D.	2,000	—	2,000
Martin Burstein, M.B.A.	2,000	—	2,000
Martin Colombatto	2,000	—	2,000
Richard Heymann	—	36,000(1)	36,000

(1) Mr. Heymann received $36,000 for services provided to us in 2017 as a part-time employee of our company. He did not receive any additional compensation as a member of our board of directors.

Non-Employee Director Compensation Policy

We have retained Compensia, a national compensation consultant, to provide our board of directors with an analysis of market data compiled from certain comparable public companies and assistance in determining compensation of directors following this offering. Our board of directors has adopted our Outside Director Compensation Policy that will be effective upon the effective date of the registration statement of which this prospectus forms a part. Our Outside Director Compensation Policy will provide that all non-employee directors will be entitled to receive the following cash compensation for their services following the completion of the offering contemplated by this prospectus:

- $40,000 retainer per year for each non-employee director;
- $40,000 retainer per year for service as chairman of the board of directors;
- $30,000 retainer per year for service as lead non-employee director;
- $20,000 retainer per year for the chairman of the audit committee or $10,000 retainer per year for each other member of the audit committee;
- $15,000 retainer per year for the chairman of the compensation committee or $7,000 retainer per year for each other member of the compensation committee; and
- $8,500 retainer per year for the chairman of the nominating and corporate governance committee or $4,500 retainer per year for each other member of the nominating and corporate governance committee.

In addition to the cash compensation structure described above, our Outside Director Compensation Policy will provide the following equity incentive compensation program for non-employee directors. Each non-employee director who first joins us (other than a director who becomes a non-employee director as a result of terminating employment with us) automatically will be granted on the first trading date on or after his or her start date as a non-employee director a one-time, initial restricted stock unit award with a value of $140,000. Further, on the date of each of our annual stockholder meetings following the effective date of the registration statement of which this prospectus forms a part, each non-employee director who is continuing as a director following our annual stockholder meeting automatically will be granted an annual restricted stock unit award with a value of $100,000. Unless otherwise determined by our board of directors or our compensation committee, the number of restricted stock units subject to such awards will be determined based on the per

share fair market value of our common stock on the applicable grant date. Each initial restricted stock unit award will vest as to 1/3rd of the award on each of the first three anniversaries of the date the director's service as a non-employee director started, subject to continued service through each relevant vesting date. Each annual restricted stock unit award will vest as to 100% of the underlying shares on the earlier of the one-year anniversary of the award's grant date or the day before the date of our annual stockholder meeting next following the award's grant date, subject to continued service through such date. In the event of a change in control of our company, all equity awards granted to a non-employee director (including those granted pursuant to our Outside Director Compensation Policy) will fully vest and become immediately exercisable, subject to continued service through such date.

In any fiscal year, a non-employee director may be paid, issued or granted cash compensation and equity awards with a total value of no greater than $500,000 (with the value of an equity award based on its grant date fair value for purposes of this limit), or the annual director limit. Equity awards or cash compensation granted to a non-employee director while he or she was an employee or consultant (other than a non-employee director) will not count toward the annual director limit.

Our Outside Director Compensation Policy will also provide for the reimbursement of our non-employee directors for reasonable, customary and documented travel expenses to attend meetings of our board of directors and committees of our board of directors.

Compensation for our non-employee directors is not limited to the equity awards and payments set forth in our Outside Director Compensation Policy. Our non-employee directors will remain eligible to receive equity awards and cash or other compensation outside of the Outside Director Compensation Policy, as may be provided from time to time at the discretion of our board of directors. For further information regarding the equity compensation of our non-employee directors, see the section of this prospectus titled "*Executive compensation-Employee Benefit and Stock Plans—2018 Equity Incentive Plan*."

Outside Director Awards in Connection with Our Initial Public Offering

In addition to the equity awards to be received under our Outside Director Compensation Policy, we expect our board of directors will grant each non-employee director serving at the time of effectiveness of our initial registration statement on Form S-8 (currently expected to consist of Mr. Saad, Mr. Colombatto, Dr. Buchbinder, Mr. Mejia, and Mr. Enquist) an award of restricted stock units pursuant to the terms of our 2018 Equity Incentive Plan and form of restricted stock unit agreement thereunder. Each award is expected to be granted effective as of the effectiveness of our initial registration statement on Form S-8 and is expected to be for a number of restricted stock units determined by dividing $140,000 by the initial public offering price in our final prospectus. Each such award is expected to vest as to 1/3 of the shares subject to each award on the first three anniversaries of the date of effectiveness of our initial registration statement on Form S-8, subject to continued service through each relevant vesting date. In the event of a change of control of our company, such awards will fully vest and become immediately exercisable, subject to continued service through such date.

Code of Ethics and Conduct

Our board of directors has adopted a written code of ethics and conduct, effective upon completion of this offering, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and agents and representatives, including consultants. Following the completion of this offering, a copy of the code of ethics and conduct will be available on our website at www.ramed.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2017, which consisted of our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, are: Dean Irwin, Jeffrey Kraws, and Melissa Burstein.

2017 Summary Compensation Table

The following table provides information regarding the compensation of our named executive officers during the year ended December 31, 2017.

Name and Principal Position[1]	Year	Salary ($)	Bonus ($)	All Other Compensation ($)	Total ($)
Dean Irwin Chief Executive Officer and Co-President	2017	231,500	—	—	231,500
Jeffrey Kraws Co-President	2017	150,000	120,000[2]	—	270,000
Melissa Burstein. Executive Vice President	2017	163,900	—	28,580[3]	192,480

(1) Titles and capacities are listed as of August 23, 2018.
(2) This amount represents a discretionary bonus earned in 2017 and paid to Mr. Kraws in 2018.
(3) This amount includes $6,000 for a car allowance to Ms. Burstein and $22,580 for a health insurance plan paid by us on behalf of Ms. Burstein. Mr. Irwin, Ms. Burstein's spouse, is covered by Ms. Burstein's health insurance plan.

Outstanding Equity Awards at December 31, 2017

There were no outstanding equity awards at December 31, 2017.

Subsequent Events

In June 2018, our board of directors approved a $340,000 discretionary bonus to Ms. Burstein for additional contributions in connection with preparing for our initial public offering. This bonus was paid, less applicable withholdings, on June 30, 2018.

In June 2018, our board of directors approved grants to certain officers, directors, employees, consultants and other service providers of (i) options to purchase an aggregate of 1,901,900 shares of our common stock at an exercise price of $28.94 per share; and (ii) restricted stock units with respect to an aggregate of 1,340,832 shares of our common stock. For award recipients other than directors, one-third of the shares subject to the options vest on the one year anniversary of the date of grant and one thirty-sixth of the shares subject to the options vest monthly thereafter, subject to the award recipient's continued service. For directors, the options vest monthly over thirty-six months following the vesting commencement date of January 1, 2017, subject to such director's continued service. The restricted stock units are scheduled to vest at various times commencing the day following the expiration of the lock-up until 10 months following the expiration of the lockup period.

The following table presents information concerning each grant of an equity award made to a named executive officer under our Compensation Plan:

Name	Principal Position	Grant Date	Shares Subject to Stock Options	Shares Subject to Restricted Stock Units
Dean Irwin	Chief Executive Officer	June 4, 2018	250,000(1)	—
		June 8, 2018	—	248,100(2)
Andrew Jackson	Chief Financial Officer and Secretary	June 4, 2018	290,000(1)	—
		June 8, 2018	—	39,482(3)
Jeffrey Kraws	Co-President	June 4, 2018	255,000(1)	—
		June 8, 2018	—	175,647(4)
		June 8, 2018	—	6,807(3)
Melissa Burstein	Executive Vice President	June 4, 2018	150,000(1)	—
		June 8, 2018	—	148,860(2)

(1) One-third of the shares subject to the option shall vest on the one year anniversary of the date of grant and one thirty-sixth of the shares subject to the option shall vest monthly thereafter, subject to the officer's continued service. If the officer's employment with the Company is terminated by the Company without cause, one-hundred percent (100%) of the shares subject to the option that have not vested shall immediately vest.

(2) Fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the first month following the expiration of the Lock-Up Period (as defined in the award agreement), fifteen percent (15%) of the restricted stock units shall vest on the 10th day of the second month following the expiration of the Lock-Up Period, fifteen percent (15%) of the Restricted Stock Units shall vest on the 15th day of the fourth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 15th day of the fifth month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the seventh month following the expiration of the Lock-Up Period, fifteen percent (15%) of the restricted stock units shall vest on the 20th day of the eighth month following the expiration of the Lock-Up Period, and ten percent (10%) of the restricted stock units shall vest on the 25th day of the tenth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

(3) Thirty-three percent (33%) of the restricted stock units shall vest on the 10th day of the third month following the expiration of the Lock-Up Period (as defined in the award agreement), thirty-three percent (33%) of the restricted stock units shall vest on the 15th day of the sixth month following the expiration of the Lock-Up Period, and thirty-four (34%) of the restricted stock units shall vest on the 20th day of the ninth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

(4) Twenty-five percent (25%) of the restricted stock units shall vest on the 10th day of the third month following the expiration of the Lock-Up Period (as defined in the award agreement), twenty-five percent (25%) of the restricted stock units shall vest on the 15th day of the fourth month following the expiration of the Lock-Up Period, twenty-five percent (25%) of the restricted stock units shall vest on the 15th day of the fifth month following the expiration of the Lock-Up Period, and twenty-five percent (25%) of the restricted stock units shall vest on the 15th day of the sixth month following the expiration of the Lock-Up Period, subject to continued service. In the event of a Change in Control (as defined in the Compensation Plan), one-hundred percent (100%) of the restricted stock units shall immediately become fully vested, subject to continued service.

Employment Arrangements with Our Executive Officers

Dean Irwin

We entered into a confirmatory employment letter with Mr. Irwin, our Chief Executive Officer, Co-President and Chief Technology Officer, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Mr. Irwin's annual base salary will be $418,000 and Mr. Irwin will be eligible annually for a target cash bonus of 100% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Irwin is also eligible for severance benefits, as more fully described in "*Management— Executive Change in Control and Severance Agreements*."

Andrew Jackson

We entered into a confirmatory employment letter with Mr. Jackson, our Chief Financial Officer and Secretary, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Mr. Jackson's annual base salary will be $348,000 and Mr. Jackson will be eligible annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Jackson is also eligible for severance benefits, as more fully described in "*Management— Executive Change in Control and Severance Agreements*."

Jeffrey Kraws

We entered into a confirmatory employment letter with Mr. Kraws, our Co-President, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Mr. Kraws' annual base salary will be $287,000 and Mr. Kraws will be eligible annually for a target cash bonus of 50% of his annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Mr. Kraws is also eligible for severance benefits, as more fully described in *"Management— Executive Change in Control and Severance Agreements."*

Melissa Burstein

We entered into a confirmatory employment letter with Ms. Burstein, our Executive Vice President, dated July 13, 2018, and effective as of the closing of our initial public offering. The confirmatory employment letter has no specific term and provides for at-will employment. Effective upon the closing of our initial public offering, Ms. Burstein's annual base salary will be $308,000 and Ms. Burstein will be eligible annually for a target cash bonus of 50% of her annual base salary, based on achieving performance objectives established by our board of directors or a committee of our board of directors. Ms. Burstein is also eligible for a car allowance equal to $500 a month, less applicable tax withholdings. Ms. Burstein is also eligible for severance benefits, as more fully described in *"Management— Executive Change in Control and Severance Agreements."*

Executive Change in Control and Severance Agreements

Our board of directors has approved a change in control and severance agreement for each of our executive officers, including our named executive officers, which agreements provide for certain severance and change in control benefits as described below. Each change in control and severance agreement supersedes any prior agreement or arrangement the executive officer may have had with us that provides for severance and/or change in control payments or benefits.

Each change in control and severance agreement has an initial term of three years, starting on the effective date of the agreement, the closing of our initial public offering. On the third anniversary of the effective date of the agreement, the agreement will renew automatically for additional one year terms unless either party provides the other party with written notice of nonrenewal at least one year prior to the date of automatic renewal. However, if a change in control (as defined in the applicable agreement) occurs when there are fewer than 12 months remaining during the initial term or during an additional term, the term of the change in control and severance agreement will extend automatically through the date that is 12 months following the date of the change in control.

If an executive officer's employment is terminated outside the period beginning 3 months before a change in control and ending 12 months (or 18 months in the case of Mr. Irwin) following a change in control, or the Change in Control Period either (1) by the Company (or any of its subsidiaries) without "cause" (excluding

by reason of death or disability) or (2) by the executive officer for "good reason" (as such terms are defined in the executive officer's change in control and severance agreement), the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to 12 months of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction); and
- payment of premiums for coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, for the executive officer and the executive officer's eligible dependents, if any, for up to 12 months, or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law.

If, within the Change in Control Period, the executive officer's employment is terminated either (1) by the Company (or any of its subsidiaries) without cause (excluding by reason of death or disability) or (2) by the executive officer for good reason, the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to 12 months (or 18 months in the case of Mr. Irwin) of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction) or if greater, at the level in effect immediately prior to the change in control);
- a lump-sum payment equal to 100% (or 150% in the case of Mr. Irwin) of the executive officer's target annual bonus as in effect for the fiscal year in which such termination occurs;
- payment of premiums for coverage under COBRA for the executive officer and the named executive officer's eligible dependents, if any, for up to 12 months (or 18 months in the case of Mr. Irwin), or taxable monthly payments for the equivalent period in the event payment of the COBRA premiums would violate or be subject to an excise tax under applicable law; and
- 100% accelerated vesting and exercisability of all outstanding equity awards and, in the case of an equity award with performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at target.

If any of the amounts provided for under these change in control and severance agreements or otherwise payable to our named executive officers would constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code and could be subject to the related excise tax, the executive officer would be entitled to receive either full payment of benefits under his or her change in control or severance agreement or such lesser amount which would result in no portion of the benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the executive officer. The change in control and severance agreements do not require us to provide any tax gross-up payments.

Employee Benefit and Stock Plans

2018 Equity Incentive Plan

Prior to the completion of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our 2018 Equity Incentive Plan, or our 2018 Plan. We expect that our 2018 Plan will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our 2018 Plan will provide for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, or Code, to our employees and any of our parent and subsidiary corporations'

employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

Authorized Shares. A total of shares of our common stock will be reserved for issuance pursuant to our 2018 Plan. In addition, the shares reserved for issuance under our 2018 Plan will also include (1) those shares reserved but unissued under our Compensation Plan (as defined below) as of the date of stockholder approval of the 2018 Plan and (2) shares of our common stock subject to or issued pursuant to awards granted under our Compensation Plan that, after the date of stockholder approval of the 2018 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2018 Plan pursuant to (1) and (2) is shares). The number of shares available for issuance under our 2018 Plan will also include an annual increase on the first day of each fiscal year beginning with our fiscal year, equal to the least of:

- shares;
- percent (%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by us due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2018 Plan (unless the 2018 Plan has terminated). With respect to stock appreciation rights, only the net shares actually issued will cease to be available under the 2018 Plan and all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2018 Plan (unless the 2018 Plan has terminated). Shares that have actually been issued under the 2018 Plan will not be returned to the 2018 Plan, except if shares issued pursuant to awards of restricted stock, restricted stock units, performance shares or performance units are repurchased by or forfeited to us, such shares will become available for future grant under the 2018 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under the 2018 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2018 Plan.

Plan Administration. Our board of directors or one or more committees appointed by our board of directors will administer our 2018 Plan. The compensation committee of our board of directors is expected to administer our 2018 Plan. In addition, if we determine it is desirable to qualify transactions under our 2018 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2018 Plan, the administrator has the power to administer our 2018 Plan and make all determinations deemed necessary or advisable for administering the 2018 Plan, including but not limited to, the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2018 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions, and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2018 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2018 Plan, including creating sub-plans, modify or amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except

no option or stock appreciation right will be extended past its original maximum term), and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash, or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Stock Options. Stock options may be granted under our 2018 Plan. The exercise price of options granted under our 2018 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any parent or subsidiary of ours) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for 3 months following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2018 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2018 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding ten years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for 12 months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for 3 months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2018 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2018 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2018 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of shares of restricted stock will have voting and dividend rights with respect to such shares upon grant

without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2018 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2018 Plan, the administrator determines the terms and conditions of restricted stock units, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2018 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance objectives established by the administrator are achieved or the awards otherwise vest. The administrator will establish performance objectives or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number or the value of performance units and performance shares to be paid out to participants. The administrator may set performance objectives based on the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance units or performance shares. Performance units will have an initial value established by the administrator on or prior to the grant date. Performance shares will have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may payout earned performance units or performance shares in cash, shares or in some combination thereof.

Outside Directors. All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2018 Plan. To provide a maximum limit on the cash compensation and equity awards that can be made to our outside directors, our 2018 Plan provides that in any given fiscal year, an outside director will not be granted cash compensation and equity awards with an aggregate value greater than $ (with the value of each equity award based on its grant date fair value as determined according to U.S. GAAP). Any cash compensation paid or awards granted to an individual for his or her services as an employee or consultant (other than as an outside director) will not count toward this limit.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2018 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments. In the event of any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of our shares or other securities, or other change in our corporate structure affecting our shares, to prevent diminution or enlargement of the benefits or potential benefits available under our 2018 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2018 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2018 Plan.

Dissolution or Liquidation. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. Our 2018 Plan provides that in the event of a merger or change in control, as defined under our 2018 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant or all awards of the same type similarly.

If a successor corporation does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not assumed or substituted in the event of a change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, in the event of a change in control, the outside director will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

Clawback. Awards will be subject to any clawback policy of ours, and the administrator also may specify in an award agreement that the participant's rights, payments, and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture, and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment; Termination. The administrator has the authority to amend, alter, suspend or terminate our 2018 Plan, provided such action does not materially impair the rights of any participant. Our 2018 Plan automatically will terminate in 2028, unless we terminate it sooner.

2018 Stock Compensation Plan

Our 2018 Stock Compensation Plan, or the Compensation Plan, was adopted by our board of directors and approved by our stockholders in June 2018.

The Compensation Plan permits the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any of our parent and subsidiary corporation's employees, and the grant of nonstatutory stock options, stock appreciation rights, restricted stock, and restricted stock units to our employees, consultants and directors and any of our parent and subsidiary corporation's employees and consultants. The Compensation Plan will be terminated prior to the completion of this offering, and thereafter we will not grant any additional awards under the Compensation Plan. However, the Compensation Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the Compensation Plan.

Authorized Shares. As of June 30, 2018, the maximum aggregate number of shares of our common stock authorized for issuance under the Compensation Plan was 3,300,000 shares, of which 61,699 shares were available for grant as of June 30, 2018. Shares may be authorized but unissued, or reacquired common stock. Shares issued pursuant to awards granted under our Compensation Plan that expire or become unexercisable without having been exercised in full, are surrendered under an exchange program, or are forfeited to or repurchased by us due to the failure to vest, as well as shares used to pay the exercise price of an award or to satisfy the tax withholdings related to an award, will become available for future grant under the Compensation Plan while the Compensation Plan remains in effect. In addition, to the extent that an award is paid out in cash rather than shares, such cash payment will not reduce the number of shares available for issuance under the Compensation Plan. Further, only shares actually issued under stock appreciation rights will reduce the shares available for issuance under the Compensation Plan.

As of June 30, 2018, options to purchase 1,898,000 shares of our common stock and restricted stock units covering 1,340,301 shares of our common stock were outstanding under the Compensation Plan.

Plan Administration. Our Compensation Plan is administered by our board of directors or a committee appointed by it. Subject to the provisions of our Compensation Plan, the administrator has the power to construe and interpret our Compensation Plan and any awards granted under it, determine the fair market value of our common stock, determine the recipients of awards, approve award agreements for use under the Compensation Plan, and determine the terms of awards, including, the number of shares subject to each award, the exercise price, the time or times at which awards may be exercised, and any vesting acceleration. The administrator may amend awards as well as implement a program under which (1) outstanding awards are surrendered or cancelled in exchange for awards of the same type (which may have higher or lower exercise prices and different terms), awards of a different type, or cash, (2) award holders have an opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, or (3) the exercise price of an outstanding award is increased or reduced. The administrator may establish rules and regulations related to the Compensation Plan, including sub-plans for satisfying applicable foreign laws or qualifying for favorable tax treatment under applicable foreign laws.

Stock Options. Prior to the completion of this offering, we may grant options under our Compensation Plan. The exercise price per share of all options must equal at least 100% of the fair market value per share of our common stock on the grant date. The term of an option may not exceed ten years. An incentive stock option to be granted to a participant who owns more than 10% of the total combined voting power of all classes of our stock or any of our parent or subsidiary corporations may not have a term in excess of five years and must have a per share exercise price of at least 110% of the fair market value per share of our common stock on the grant date. After the termination of service of an employee, director or consultant due to death or disability, his or her option will remain exercisable for 6 months (or such longer period of time specified in the option agreement) following the termination of service. In all other cases, the option will remain exercisable for 30 days following a termination of service (or such longer period of time specified in the option agreement). An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of the Compensation Plan, the administrator determines all other terms of options, including vesting and the method of payment of the exercise price of an option.

Stock Appreciation Rights. Prior to the completion of this offering, we may grant stock appreciation rights under our Compensation Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the grant date and the exercise date. The per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share of our common stock on the grant date. The term of a stock appreciation right may not exceed 10 years. Stock appreciation rights are

generally subject to the same post-termination exercise period rules as options. Subject to the provisions of our Compensation Plan, the administrator determines all other terms of stock appreciation rights, including when such rights vest and become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination of both.

Restricted Stock. Prior to the completion of this offering, we may grant restricted stock under our Compensation Plan. Restricted stock awards are grants of shares of our common stock that may be subject to various restrictions, including restrictions on transferability and forfeiture provisions. Subject to the terms of our Compensation Plan, the administrator will determine the number of shares of restricted stock granted and other terms and conditions of such awards. The administrator may impose whatever conditions to vesting it determines to be appropriate, and may, in its sole discretion, accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that have not vested are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Prior to the completion of this offering, we may grant restricted stock units under our Compensation Plan. Restricted stock units are bookkeeping entries with each unit representing an amount equal to the fair market value of one share of our common stock. The administrator determines the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. The administrator in its sole discretion may reduce or waive any vesting criteria. The administrator determines in its sole discretion whether restricted stock units will be settled in cash, shares of our common stock, or a combination of both. Restricted stock units that do not vest will be forfeited by the recipient and will return to us.

Non-Transferability of Awards. Unless the administrator provides otherwise, our Compensation Plan generally does not allow for the transfer of awards other than by will or the laws of descent or distribution, and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of our shares or other securities, or other change in our corporate structure affecting our shares, to prevent diminution or enlargement of the benefits or potential benefits to be made available under the Compensation Plan, the administrator will adjust the number and class of shares that may be delivered under our Compensation Plan and/or the number, class, and price of shares covered by each outstanding award. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable prior to the proposed transaction, and to the extent not previously exercised, awards will terminate immediately prior to the closing of the proposed transaction.

Merger or Change in Control. Our Compensation Plan provides that in the event of a merger or change in control, as defined under our Compensation Plan, each outstanding award will be treated as the administrator determines, including, without limitation, that each award will be assumed or a substantially equivalent award substituted by the acquiring or succeeding corporation (or an affiliate thereof). The administrator is not required to treat all awards similarly in the transaction.

If a successor corporation does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met, in all cases unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to

the participant. If an option or stock appreciation right is not assumed or substituted in the event of a change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

Forfeiture Events. Awards will be subject to any clawback policy of ours, and the administrator may specify in an award agreement that the participant's rights, payments, and benefits with respect to an award will be subject to reduction, cancellation, forfeiture, or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and any amounts paid under the award pursuant to the terms of such clawback policy or to comply with applicable laws.

Amendment; Termination. Our board of directors has the authority to amend, alter, suspend or terminate the Compensation Plan, so long as such action does not impair the rights of any participant, unless mutually agreed in writing otherwise between us and the affected participant. The Compensation Plan will be terminated prior to the completion of this offering, and thereafter we will not grant any additional awards under the Compensation Plan. However, the Compensation Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the Compensation Plan.

2018 Employee Stock Purchase Plan

Prior to the completion of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our 2018 Employee Stock Purchase Plan, or our ESPP. We expect that our ESPP will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. We believe that allowing our employees to participate in our ESPP will provide them with a further incentive towards promoting our success and accomplishing our corporate goals.

Authorized Shares. A total of shares of our common stock will be available for sale under our ESPP. The number of shares of our common stock that will be available for sale under our ESPP also includes an annual increase on the first day of each fiscal year beginning with our fiscal year, equal to the least of:

- shares;
- percent (%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as the administrator may determine.

Plan Administration. We expect that the compensation committee of our board of directors will administer our ESPP and will have full and exclusive discretionary authority to construe, interpret and apply the terms of the ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the ESPP, designate our subsidiaries and affiliates as participating in the ESPP, determine eligibility, adjudicate all disputed claims filed under the ESPP and establish procedures that it deems necessary for the administration of the ESPP, including, but not limited to, adopting such procedures and sub-plans as are necessary or appropriate to permit participation in the ESPP by employees who are foreign nationals or employed outside the United States. The administrator's findings, decisions and determinations are final and binding on all participants to the full extent permitted by law.

Eligibility. Generally, all of our employees will be eligible to participate if they are customarily employed by us, or any participating subsidiary or affiliate, for at least 20 hours per week and more than five months in any calendar year. The administrator, in its discretion, may, prior to an enrollment date,

for all options to be granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date, (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator), (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator), (iv) is a highly compensated employee within the meaning of Section 414(q) of the Code or (v) is a highly compensated employee within the meaning of Section 414(q) of the Code with compensation above a certain level or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our ESPP if such employee:

- immediately after the grant would own capital stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of capital stock of ours or of any parent or subsidiary of ours; or
- holds rights to purchase shares of our common stock under all employee stock purchase plans of ours or any parent or subsidiary of ours that accrue at a rate that exceeds $25,000 worth of shares of our common stock for each calendar year in which such rights are outstanding at any time.

Offering Periods. Our ESPP will include a component that allows us to make offerings intended to qualify under Section 423 of the Code and a component that allows us to make offerings not intended to qualify under Section 423 of the Code to designated companies, as described in our ESPP. Our ESPP will provide for offering periods. The offering periods will be scheduled to start on the first trading day on or after and of each year, except the first offering period will start on the first trading day on or after the effective date of the registration statement of which this prospectus forms a part and will end on the last trading day on or before . Each offering period will include purchase periods, which unless the administrator provides otherwise, will (i) start on the first trading day on or after and and (ii) end on the last trading day on or before of the same year and of the following year, respectively, except that the first purchase period under our ESPP will start on the first trading day on or after the effective date of the registration statement of which this prospectus forms a part and will end on the last trading day on or before .

Contributions. Our ESPP will permit participants to purchase shares of our common stock through contributions (in the form of payroll deductions or otherwise to the extent permitted by the administrator) of up to % of their eligible compensation, which includes a participant's base straight time gross earnings but excludes payments for incentive compensation, bonuses, payments for overtime and shift premium, equity compensation income and other similar compensation. Unless otherwise determined by the administrator, a participant may make a one-time decrease (but not increase) to the rate of his or her contributions to 0% during a purchase period.

Exercise of Purchase Right. Amounts contributed and accumulated by the participant will be used to purchase shares of our common stock at the end of each six-month purchase period. A participant may purchase a maximum of shares of our common stock during a purchase period. The purchase price of the shares will be % of the lower of the fair market value of our common stock on the first trading day of the offering period or on the exercise date. If the fair market value of our common stock on the exercise date is less than the fair market value on the first trading day of the offering period, participants will be automatically withdrawn from such offering period immediately following their purchase of shares of our common stock on the purchase date and will be automatically re-enrolled in the next offering period. Participants may end their participation at any time during an offering period

and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation ends automatically upon termination of employment with us.

Non-Transferability. A participant may not transfer contributions credited to his or her account nor any rights granted under our ESPP other than by will, the laws of descent and distribution or as otherwise provided under our ESPP.

Merger or Change in Control. Our ESPP provides that in the event of a merger or change in control, as defined under our ESPP, a successor corporation (or a parent or subsidiary of the successor corporation) will assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period with respect to which the purchase right relates will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment; Termination. The administrator will have the authority to amend, suspend or terminate our ESPP. Our ESPP automatically will terminate in 2038, unless we terminate it sooner.

Executive Incentive Compensation Plan

In July 2018, our board of directors adopted an Executive Incentive Compensation Plan, or the Bonus Plan. The Bonus Plan will be administered by a committee appointed by our board of directors. Unless and until our board of directors determines otherwise, our compensation committee will be the administrator of the Bonus Plan. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, determined by our compensation committee, based upon performance goals established by our compensation committee. Our compensation committee, in its sole discretion, will establish a target award for each participant under the Bonus Plan, which may be expressed as a percentage of the participant's average annual base salary for the applicable performance period, a fixed dollar amount, or such other amount or based on such other formula as our compensation committee determines to be appropriate.

Under the Bonus Plan, our compensation committee will determine the performance goals applicable to awards, which goals may include, without limitation: attainment of research and development milestones, bookings, business divestitures and acquisitions, cash flow, cash position, contract awards or backlog, customer renewals, customer retention rates from an acquired company, subsidiary, business unit or division, earnings (which may include earnings before interest and taxes, earnings before taxes, and net taxes), earnings per share, expenses, gross margin, growth in stockholder value relative to the moving average of the S&P 500 Index or another index, internal rate of return, market share, net income, net profit, net sales, new product development, new product invention or innovation, number of customers, operating cash flow, operating expenses, operating income, operating margin, overhead or other expense reduction, product defect measures, product release timelines, productivity, profit, retained earnings, return on assets, return on capital, return on equity, return on investment, return on sales, revenue, revenue growth, sales results, sales growth, stock price, time to market, total stockholder return, working capital, and individual objectives such as peer reviews or other subjective or objective criteria. As determined by our compensation committee, the performance goals may be based on generally accepted accounting principles, or GAAP, or non-GAAP results and any actual results may be adjusted by our compensation committee for one-time items or unbudgeted or unexpected items and/or payments of actual awards under the Bonus Plan when determining whether the performance goals have been met. The goals may be on the basis of any factors our compensation committee determines relevant, and may be on an individual, divisional, business unit, segment or company-wide basis. Any criteria used may be measured on such basis as our compensation committee determines. The performance goals may differ

from participant to participant and from award to award. Our compensation committee also may determine that a target award or a portion thereof will not have a performance goal associated with it but instead will be granted (if at all) in the compensation committee's sole discretion.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool. The actual award may be below, at or above a participant's target award, in our compensation committee's discretion. Our compensation committee may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and it will not be required to establish any allocation or weighting with respect to the factors it considers.

Actual awards will generally be paid in cash (or its equivalent) in a single lump sum only after they are earned and approved by our compensation committee. Our compensation committee has the right, in its sole discretion, to settle an actual award with a grant of an equity award under our then-current equity compensation plan, which equity award may have such terms and conditions, including vesting, as our compensation committee determines in its sole discretion. Unless otherwise determined by our compensation committee, to earn an actual award, a participant must be employed by us (or an affiliate of us, as applicable) through the date the actual award is paid. Payment of bonuses occurs as soon as administratively practicable after the end of the applicable performance period, but no later than the dates set forth in the Bonus Plan.

Our board of directors will have the authority to amend or terminate the Bonus Plan provided such action does not alter or impair the existing rights of any participant with respect to any earned actual award without the participant's consent. The Bonus Plan will remain in effect until terminated in accordance with the terms of the Bonus Plan.

Limitations on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective immediately prior to the completion of this offering, will provide that we will indemnify our directors and officers and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Any amendment to, or repeal of, these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission, or claim that occurred or arose prior to that amendment or repeal. If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be

empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into and expect to continue to enter into agreements to indemnify each member of our board of directors and each of our officers. These agreements provide for the indemnification of our directors and officers for certain expenses and liabilities incurred in connection with any action, suit, proceeding or alternative dispute resolution mechanism, or hearing, inquiry or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent or fiduciary of another entity. In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Moreover, a stockholder’s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

We have obtained insurance policies under which, subject to the limitations of the policies, coverage is provided to our directors and executive officers against losses arising from claims made by reason of breach of fiduciary duty or other wrongful acts as a director or executive officer and to us with respect to payments that may be made by us to these directors and executive officers pursuant to our indemnification obligations or otherwise as a matter of law.

Certain of our non-employee directors may, through their relationships with their employers, be insured and/or indemnified against certain liabilities incurred in their capacity as members of our board of directors.

The underwriting agreement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Emerging Growth Company Status

As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the director and executive officer compensation arrangements and indemnification arrangements discussed above in the sections titled "*Management*" and "*Executive compensation*" the following is a description of each transaction since January 1, 2015, and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock, or any immediate family member of or person sharing the household with any of these individuals or entities, had or will have a direct or indirect material interest.

Short Term Loan

In August 2016, Noteworthy Advisors, Inc., a corporation owned by Richard Heymann, a member of our board of directors, loaned us $130,000 pursuant to a short term loan. In September 2016, we repaid $131,300, which was the aggregate outstanding principal and interest of $1,300 due under the loan.

Certain Family Relationships

There are certain relationships between certain of our directors and executive officers. Our co-founders, Dean Irwin, who is currently serving as our Chief Executive Officer, Co-President, Chief Technology Officer and Chairman of the board of directors, and Melissa Burstein, who is currently serving as our Executive Vice President and a member of our board of directors, are married. Additionally, Martin Burstein, who is currently serving as our director, is Ms. Burstein's father and Mr. Irwin's father-in-law. Mr. Burstein intends to resign from our board of directors contingent upon and effective immediately prior to the effectiveness of this offering.

Policies and Procedures for Transactions with Related Persons

Our audit committee will have the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. The charter of our audit committee that will be in effect upon the completion of this offering will provide that our audit committee shall review and approve or disapprove in advance any related party transaction.

We have adopted a formal written policy, effective upon the completion of this offering, that provides that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our audit committee, or other independent members of our board of directors if it is inappropriate for our audit committee to review such transaction due to a conflict of interest, subject to certain exceptions. Any request for us to enter into a transaction with an executive officer, director, principal stockholder, or any of their immediate family members or affiliates, in which the amount involved exceeds $120,000 must first be presented to our audit committee for review, consideration and approval, subject to certain exceptions. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Transactions with related parties have been disclosed in our financial statements and the related notes, and elsewhere in this prospectus as applicable.

Sales of Securities

The following table sets forth a summary of the sale and issuance of our securities to related persons since January 1, 2015 in which the amount involved exceeded $120,000, other than in connection with compensation arrangements which are described elsewhere in this prospectus under the section captioned "*Executive and director compensation*." For a description of beneficial ownership of our securities, see the section of this prospectus captioned "*Security ownership of certain beneficial owners and management.*"

Purchaser Name	Shares of Common Stock
Martin Colombatto(1)	37,500

(1) Consists of 37,500 shares of Company common stock issued to M Colombatto Trust in December 2016 at a price of $8.00 per share in exchange for an aggregate cash purchase price of $300,000. Martin Colombatto, the sole trustee of M Colombatto Trust, is a member of our board of directors.

Control by Officers and Directors

Our officers and directors and their affiliates beneficially own, in the aggregate, approximately 62% of our outstanding common stock as of August 23, 2018. As a result, in certain circumstances, these stockholders acting together may be able to determine matters requiring approval of our stockholders, including the election of our directors, or they may delay, defer or prevent a change in control of us. See the section of this prospectus captioned "*Security ownership of certain beneficial owners and management*" below.

Indemnification of Officers and Directors

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws that will be effective upon the completion of this offering require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law. See the section of this prospectus captioned "*Executive compensation—limitations on liability and indemnification matters*" above.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of August 23, 2018, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors and director nominees; and
- all of our executive officers and directors as a group.

The percentage of beneficial ownership information shown in the table prior to this offering is based on 8,204,851 shares of common stock outstanding as of August 23, 2018, and assumes no participation in this offering by the parties below. The percentage of beneficial ownership shown in the table after this offering is based upon shares of common stock outstanding after the close of this offering, assuming the sale of shares of common stock by us in the offering and no exercise of the underwriters' over-allotment option.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of our common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of August 23, 2018, and restricted stock units that are scheduled to vest within 60 days of August 23, 2018. These shares are deemed to be outstanding and beneficially owned by the person holding those options and restricted stock units for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address of each of the individuals and entities named in the table below is c/o Ra Medical Systems, Inc., 2070 Las Palmas Drive, Carlsbad, California 92011. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Name of Beneficial Owner	Shares	Percentage Beneficial Ownership Prior to the Offering	Percentage Beneficial Ownership After the Offering
Directors, Named Executive Officers, and 5% Stockholders:			
Dean Irwin[1]	2,803,852	34.18%	
Melissa Burstein, M.B.A.[2]	2,803,852	34.18%	
Jeffrey Kraws	—	*	*
Martin Burstein, M.B.A.[3]	1,979,000	24.05%	
Richard Heymann[4]	295,011	3.60%	
Maurice Buchbinder, M.D.[5]	26,500	*	*
Martin Colombatto[6]	62,000	*	*
Richard Mejia, Jr.[7]	—	*	*
Mark E. Saad[8]	—	*	*
William R. Enquist, Jr.[9]	—	*	*
All directors and executive officers as a group (11 persons)[10]	5,166,363	62.41%	

* Represents beneficial ownership of less than one percent

(1) Consists of 2,803,852 shares held of record by the Dean Irwin and Melissa Burstein Family Trust. Dean Irwin, a member of our board of directors and named executive officer, and Melissa Burstein, a member of our board of directors and named executive officer, each serve as co-trustees of the Dean Irwin and Melissa Burstein Family Trust.

(2) Consists of 2,803,852 shares held of record by the Dean Irwin and Melissa Burstein Family Trust. Dean Irwin, a member of our board of directors and named executive officer, and Melissa Burstein, a member of our board of directors and named executive officer, each serve as co-trustees of the Dean Irwin and Melissa Burstein Family Trust.

(3) Consists of (i) 24,500 shares of common stock subject to options exercisable within 60 days of August 23, 2018; (ii) 1,604,500 shares held of record by Martin Burstein Living Trust dated January 28, 2002 ("M. Burstein Trust"); and (iii) 350,000 shares held of record by Karen Jorgensen Burstein Family Trust Dated November 10, 2000 ("K. Burstein Trust"). Martin Burstein, a member of our board of directors, is a trustee of the M. Burstein Trust. Karen Jorgensen Burstein, Martin Burstein's spouse, is a trustee of the K. Burstein Trust.

(4) Consists of (i) 260,000 shares held of record by Richard Heymann; (ii) 20,000 shares held of record by Heymann Family Trust, of which Mr. Heymann serves as a trustee; (iii) 13,761 shares held of record by Balanced Security Pension Plan FBO Rick Heymann; and (iv) 1,250 shares held of record by Balance Security Pension Plan FBO Christy Heymann Roth, Mr. Heymann's spouse.

(5) Consists of (i) 24,500 shares of common stock subject to options exercisable within 60 days of August 23, 2018; and (ii) 2,000 shares held of record.

(6) Consists of (i) 24,500 shares of common stock subject to options exercisable within 60 days of August 23, 2018; and (ii) 37,500 shares held of record by M. Colombatto Trust. Martin Colombatto, a member of our board of directors, serves as trustee of the M. Colombatto Trust.

(7) Mr. Mejia joined our board of directors in July 2018.

(8) Mr. Saad joined our board of directors in July 2018.

(9) Mr. Enquist joined our board of directors in July 2018.

(10) Consists of 5,092,863 shares of common stock held and options to purchase 73,500 shares of common stock that are exercisable within 60 days of August 23, 2018.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes certain terms of our capital stock and certain provisions of our amended and restated certificate of incorporation, as will be in effect immediately prior to the completion of this offering. We have adopted an amended and restated certificate of incorporation and amended and restated bylaws to be in effect in connection with the completion of this offering, and this description summarizes certain of the provisions that are included in those documents. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed with the SEC as exhibits to the registration statement of which this prospectus is a part, and to the applicable provisions of Delaware law.

Immediately prior to the completion of this offering, our authorized capital stock will consist of 310,000,000 shares of capital stock, of which 300,000,000 will be designated as common stock, $0.0001 par value per share, and 10,000,000 shares will be designated as preferred stock, $0.0001 par value per share. Our board of directors is authorized, without stockholder approval, except as required by the listing standards of the NYSE, to issue shares of our preferred stock. As of June 30, 2018, there were 8,204,851 shares of common stock issued and outstanding and there were 184 holders of record of our common stock.

Common Stock

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of our stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available. See the section captioned "*Dividend Policy*" for additional information. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering, our board of directors will have the authority, without further action by the stockholders, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series. Our board of directors may designate the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock or delaying, deterring or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

Registration Rights

We have not granted any registration rights.

Anti-Takeover Effects of Delaware law and our Certificate of Incorporation and Bylaws

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws to be effective immediately prior to the completion of this offering will contain provisions that could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions and certain provisions of Delaware law, which are summarized below, may have the effect of discouraging takeover bids, coercive or otherwise. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Issuance of Undesignated Preferred Stock. As discussed above under "*Description of Capital Stock—Preferred Stock*," our board of directors will have the ability to designate and issue preferred stock with voting or other rights or preferences that could deter hostile takeovers or delay changes in our control or management.

Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting. Our amended and restated certificate of incorporation will provide that our stockholders may not act by written consent. This limit on the ability of stockholders to act by written consent may lengthen the amount of time required to take stockholder actions. As a result, the holders of a majority of our capital stock would not be able to amend the amended and restated bylaws or remove directors without holding a meeting of stockholders called in accordance with the amended and restated bylaws. In addition, our amended and restated bylaws will provide that special meetings of the stockholders may be called only by the chairperson of the board, our chief executive officer or president (in the absence of a chief executive officer) or a majority of our board of directors. A stockholder may not call a special meeting, which may delay the ability of our stockholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors. These advance notice procedures may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed and may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempt to obtain control of our company.

Board Classification. Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve for a three-year term. For more information on the classified board of directors, see "*Management—Board of Directors*." Our classified board of directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Election and Removal of Directors. Our amended and restated certificate of incorporation and amended and restated bylaws will contain provisions that establish specific procedures for appointing and removing members of our board of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, vacancies and newly created directorships on our board of directors may be filled only by a majority of the directors then serving on the board of directors.

Under our amended and restated certificate of incorporation and amended and restated bylaws, directors may be removed only for cause by the affirmative vote of the holders of a majority of the shares then entitled to vote at an election of directors.

No Cumulative Voting. The Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and amended and restated bylaws will not expressly provide for cumulative voting. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board of directors' decision regarding a takeover.

***Amendment of Charter Provision*.** Any amendment of the above provisions in our amended and restated certificate of incorporation would require approval by holders of at least 66 2/3% of our then outstanding capital stock entitled to vote, voting together as a single class.

Delaware Anti-Takeover Statute. We will be subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts.

These provisions might also have the effect of preventing changes in our management. It is also possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Choice of Forum. Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty; (iii) any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate or our amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and (v) any action asserting a claim against us that is governed by the internal-affairs doctrine. Our amended and restated certificate of incorporation will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is 718-921-8300. Our shares of common stock will be issued in uncertificated form only, subject to limited circumstances.

Market Listing

We have applied to list our common stock on the NYSE under the symbol "RMED."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to the completion of this offering, there has been no public market for our common stock, and we cannot assure you that a liquid trading market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of shares of common stock, including shares issued upon the exercise of outstanding options and upon the vesting of outstanding restricted stock units, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital in the future. The effect of sales of our common stock in the public market may be exacerbated by the relatively small public float of our common stock following this offering. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of the date of this prospectus, and assuming the sale of all shares offered, upon completion of this offering, shares of common stock will be outstanding. All of the securities sold by us in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, unless held by our "affiliates," as that term is defined under Rule 144 under the Securities Act.

The remaining shares of common stock outstanding upon the closing of this offering will be "restricted securities," as defined under Rule 144 of the Securities Act. Restricted securities may be sold in the U.S. public market only if registered or if they qualify for an exemption from registration, including by reason of Rule 144 or 701 under the Securities Act, which rules are summarized below. All of our executive officers, directors and holders of approximately % of our outstanding voting common stock have entered into market standoff agreements with us or into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus. Subject to the lock-up agreements described below, the applicable conditions of Rule 144 or Rule 701 and our insider trading policy, these restricted securities will generally become available for sale in the public market as follows:

- restricted shares will be eligible for sale in the public market upon the completion of this offering under Rule 144; and
- beginning 181 days after the date of this prospectus, the remainder of the shares of our common stock will be eligible for sale in the public market from time to time thereafter, subject in some cases to the volume and other restrictions of Rule 144, our insider trading policy, and certain of our market standoff agreements, as described below.

Lock-Up Agreements

We, our officers and directors and holders of approximately % of our outstanding voting of our common stock, have agreed that, subject to certain exceptions and under certain conditions, for a period of 180 days after the date of this prospectus, we and they will not, without the prior written consent of Piper Jaffray & Co. and Cantor Fitzgerald & Co., dispose of or hedge any shares or any securities convertible into or exchangeable for shares of our capital stock. These agreements are described in the section captioned "*Underwriters*" located elsewhere in this prospectus.

Rule 144

In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock to be sold

for at least six months, would be entitled to sell an unlimited number of shares of our common stock, provided current public information about us is available. In addition, under Rule 144, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares of our common stock to be sold for at least one year, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months are entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; and
- the average weekly trading volume of our common stock on during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale, or if no such notice is required, the date of receipt of the order to execute the sale.

Sales of restricted shares under Rule 144 by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares are required to wait until ninety (90) days after the date of this prospectus before selling their shares under Rule 701.

Registration Statement on Form S-8

As of June 30, 2018, options to purchase an aggregate of 1,898,000 shares of our common stock were outstanding, and restricted stock units covering 1,340,301 shares of our common stock were outstanding. Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register shares of our common stock issued or reserved for issuance under our equity compensation plans. The registration statement on Form S-8 will become effective immediately upon filing, and shares covered by such registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. See the section captioned "*Executive compensation—Employee benefit and stock plans*" for additional information.

Registration Rights

We have not granted any registration rights.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF THE OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK

The following is a general discussion of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) with respect to their ownership and disposition of our common stock purchased in this offering. This discussion is for general information only, is not tax advice and does not purport to be a complete analysis of all the potential tax considerations. This discussion is based upon the provisions of the United States Internal Revenue Code of 1986, as amended, or the Code, existing and proposed Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all in effect as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This discussion does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal gift and estate tax laws. In addition, this discussion does not address any tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- persons subject to the alternative minimum tax or the Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons whose functional currency is not the U.S. dollar;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any warrant or option or otherwise as compensation;
- persons who hold or receive our common stock pursuant to conversion rights under convertible instruments;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code; or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership, entity or arrangement classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, entities classified as partnerships for U.S. federal income tax purposes and other pass-through entities that hold our common stock, as well as partners or members in such entities, should consult their tax advisors.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax laws or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty. In addition, significant changes in U.S. federal income tax laws were recently enacted. You should consult with your tax advisor with respect to such changes in U.S. tax law as well as potentially conforming changes in state tax laws.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder if you are any holder of our common stock other than a partnership (or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) or:

- an individual who is a citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust if it (x) is subject to the primary supervision of a U.S. court and one or more U.S. persons have the authority to control all substantial decisions of the trust or (y) has made a valid election under applicable Treasury Regulations to be treated as a U.S. person.

Distributions

As described in the section captioned "*Dividend policy*," we have never declared or paid cash dividends on our capital stock and do not anticipate paying any dividends on our capital stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "*—Gain on Disposition of Our Common Stock*."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the United States) are generally exempt from the withholding tax described in the previous paragraph, subject to the discussion below on backup withholding. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits,

subject to an applicable income tax treaty providing otherwise. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

If you hold our common stock through a financial institution or other agent acting on your behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. You may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Disposition of Common Stock

Subject to the discussion below on backup withholding and on common stock held by or through foreign entities, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the United States);
- you are a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, your common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 24% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed and appropriate IRS Form W-8 or otherwise meets documentary evidence requirements for establishing non- U.S. holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the U.S. through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, you may be able to obtain a refund or credit from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act and the rules and regulations promulgated thereunder, collectively FATCA, generally impose withholding tax at a rate of 30% on dividends on, and gross proceeds from the sale or other disposition of, our common stock paid to a “foreign financial institution” (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a “non-financial foreign entity” (as specially defined under these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. You should consult your tax advisors regarding the possible implications of FACTA on your investment in our common stock.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

We are offering the shares of our common stock described in this prospectus through the underwriters named below. Piper Jaffray & Co. and Cantor Fitzgerald & Co. are acting as joint book-running managers of this offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase, and we have agreed to sell to the underwriters, the number of shares of common stock listed next to its name in the following table.

Underwriters	Number of Shares
Piper Jaffray & Co.	
Cantor Fitzgerald & Co.	
SunTrust Robinson Humphrey, Inc.	
Nomura Securities International, Inc.	
Maxim Group LLC	
Total	

The underwriting agreement provides that the underwriters must buy all of the shares of common stock if they buy any of them. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares as described below.

Our common stock is offered subject to a number of conditions, including:

- receipt and acceptance of our common stock by the underwriters; and
- the underwriters' right to reject orders in whole or in part.

We have been advised by the representatives that the underwriters intend to make a market in our common stock but that they are not obligated to do so and may discontinue making a market at any time without notice.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically.

Option to Purchase Additional Shares

We have granted the underwriters an option to buy up to an aggregate of additional shares of our common stock. The underwriters have 30 days from the date of this prospectus to exercise this option. If the underwriters exercise this option, they will each purchase additional shares of common stock approximately in proportion to the amounts specified in the table above.

Underwriting Discount

Shares sold by the underwriters to the public will initially be offered at the initial offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. The underwriters may offer the shares through one or more of their affiliates or selling agents. If all the shares are not sold at the initial public offering price, the representatives may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares at the prices and upon the terms stated therein.

The following table shows the per share and total underwriting discount we will pay to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase up to additional shares.

	No Exercise	Full Exercise
Per share	$	$
Total	$	$

We estimate that the total expenses of the offering payable by us, not including the underwriting discount, will be approximately $ million.

No Sales of Similar Securities

We, our executive officers and directors, and holders of approximately % of our outstanding voting common stock have entered into lock-up agreements with the underwriters. Under the lock-up agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of Piper Jaffray & Co. and Cantor Fitzgerald & Co., offer, sell, contract to sell, pledge, or otherwise dispose of, directly or indirectly, or hedge our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus.

Piper Jaffray & Co. and Cantor Fitzgerald & Co. may, at any time and in their sole discretion, release some or all the securities from these lock-up agreements. If the restrictions under the lock-up agreements are waived, shares of our common stock may become available for resale into the market, subject to applicable law, which could reduce the market price of our common stock.

Indemnification

We have agreed to indemnify the several underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters may be required to make in respect of those liabilities.

New York Stock Exchange

We have applied to have our common stock approved for listing on the NYSE under the symbol "RMED."

Price Stabilization, Short Positions

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed

a specified maximum. These transactions may also include making short sales of our common stock, which involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering and purchasing shares of common stock on the open market to cover short positions created by short sales. Short sales may be "covered short sales," which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked short sales," which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on the NYSE, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. Neither we, nor any of the underwriters make any representation that the underwriters will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

Determination of Offering Price

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation among us and the representatives of the underwriters. The principal factors to be considered in determining the initial public offering price include:

- the information set forth in this prospectus and otherwise available to the representatives;
- our history and prospects and the history and prospects for the industry in which we compete;
- our past and present financial performance;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities market at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

The estimated public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock or that the common stock will trade in the public market at or above the initial public offering price.

Affiliations

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and their affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of us. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Notice to Prospective Investors in Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI

33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "**Relevant Member State**") an offer to the public of any shares which are the subject of the offering contemplated by this prospectus (the "**Shares**") may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Directive;

(b) by the Managers to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of Lead Manager for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of Shares shall result in a requirement for the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "**offer to the public**" in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. The expression "**Prospectus Directive**" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression "**2010 PD Amending Directive**" means Directive 2010/73/EU.

The EEA selling restriction is in addition to any other selling restrictions set out in this prospectus.

Notice to Prospective Investors in Australia

This prospectus is not a formal disclosure document and has not been, nor will be, lodged with the Australian Securities and Investments Commission. It does not purport to contain all information that an investor or their professional advisers would expect to find in a prospectus or other disclosure document (as defined in the Corporations Act 2001 (Australia)) for the purposes of Part 6D.2 of the Corporations Act 2001 (Australia) or in a product disclosure statement for the purposes of Part 7.9 of the Corporations Act 2001 (Australia), in either case, in relation to the securities.

The securities are not being offered in Australia to "retail clients" as defined in sections 761G and 761GA of the Corporations Act 2001 (Australia). This offering is being made in Australia solely to "wholesale clients" for the purposes of section 761G of the Corporations Act 2001 (Australia) and, as such, no prospectus, product disclosure statement or other disclosure document in relation to the securities has been, or will be, prepared.

This prospectus does not constitute an offer in Australia other than to persons who do not require disclosure under Part 6D.2 of the Corporations Act 2001 (Australia) and who are wholesale clients for the purposes of section 761G of the Corporations Act 2001 (Australia). By submitting an application for our securities, you represent and warrant to us that you are a person who does not require disclosure

under Part 6D.2 and who is a wholesale client for the purposes of section 761G of the Corporations Act 2001 (Australia). If any recipient of this prospectus is not a wholesale client, no offer of, or invitation to apply for, our securities shall be deemed to be made to such recipient and no applications for our securities will be accepted from such recipient. Any offer to a recipient in Australia, and any agreement arising from acceptance of such offer, is personal and may only be accepted by the recipient. In addition, by applying for our securities you undertake to us that, for a period of 12 months from the date of issue of the securities, you will not transfer any interest in the securities to any person in Australia other than to a person who does not require disclosure under Part 6D.2 and who is a wholesale client.

Notice to Prospective Investors in Hong Kong

The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our securities may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to "professional investors" within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the SFO and any rules made thereunder.

Notice to Prospective Investors in Japan

Our securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and our securities will not be offered or sold, directly or indirectly, in Japan, or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan, or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This document has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this document and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of our securities may not be circulated or distributed, nor may our securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "**SFA**"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where our securities are subscribed or purchased under Section 275 by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired our securities pursuant to an offer made under Section 275 except:

(1) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(2) where no consideration is or will be given for the transfer;

(3) where the transfer is by operation of law; or

(4) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Switzerland

The Prospectus does not constitute an issue prospectus pursuant to Article 652a or Article 1156 of the Swiss Code of Obligations ("CO") and the shares will not be listed on the SIX Swiss Exchange. Therefore, the Prospectus may not comply with the disclosure standards of the CO and/or the listing rules (including any prospectus schemes) of the SIX Swiss Exchange. Accordingly, the shares may not be offered to the public in or from Switzerland, but only to a selected and limited circle of investors, which do not subscribe to the shares with a view to distribution.

Notice to Prospective Investors in United Kingdom

This prospectus is only being distributed to and is only directed at: (1) persons who are outside the United Kingdom; (2) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (3) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons falling within (1)-(3) together being referred to as "relevant persons"). The shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Diego, California. The underwriters are being represented by Cooley LLP, New York, New York, in connection with this offering.

EXPERTS

The financial statements as of and for the years ended December 31, 2016 and 2017 included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to the restatement of the 2016 financial statements). Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at www.ramed.com. Upon completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

INDEX TO FINANCIAL STATEMENTS

RA MEDICAL SYSTEMS, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of
Ra Medical Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ra Medical Systems, Inc. (the "Company") as of December 31, 2016 and 2017, the related statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes to the financial statements (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2016 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Restatement of the 2016 Financial Statements

As discussed in Note 3 to the financial statements, the accompanying 2016 financial statements have been restated.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
May 18, 2018 (August 24, 2018 as to the effects of the Company's reincorporation in Delaware as described in Note 1 and Note 15)

We have served as the Company's auditor since 2018.

Ra Medical Systems, Inc.

Balance Sheets
(in thousands, except share and per share data)

	December 31, 2016 (restated)	2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,921	$ 8,237
Accounts receivable, net	393	517
Inventories, net	870	1,196
Prepaid expenses and other current assets	124	92
Total current assets	5,308	10,042
Property and equipment, net	506	1,159
Other non-current assets	28	68
TOTAL ASSETS	$ 5,842	$ 11,269
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 473	$ 426
Accrued expenses	419	324
Current portion of deferred revenue	1,744	1,714
Current portion of equipment financing	42	44
Other current liabilities	32	125
Total current liabilities	2,710	2,633
Deferred revenue	836	775
Equipment financing	65	19
Stock-based compensation liability	2,611	15,376
Other liabilities	—	81
Total liabilities	6,222	18,884
Commitments and contingencies (Note 13)		
Stockholders' Deficit		
Common stock, $0.0001 par value, 25,000,000 shares authorized; 7,462,720 and 7,888,170 issued and outstanding, respectively	1	1
Additional paid-in capital	11,243	21,773
Accumulated deficit	(11,624)	(29,389)
Total stockholders' deficit	(380)	(7,615)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 5,842	$ 11,269

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Operations
(in thousands, except per share data)

	Year ended December 31,	
	2016 (restated)	2017
Net revenue		
Product sales	$ 3,817	$ 3,067
Service and other	2,159	2,803
Total net revenue	5,976	5,870
Cost of revenue		
Product sales	2,289	2,854
Service and other	849	1,311
Total cost of revenue	3,138	4,165
Gross profit	2,838	1,705
Operating expenses		
Selling, general and administrative	5,321	14,947
Research and development	1,715	4,518
Total operating expenses	7,036	19,465
Operating loss	(4,198)	(17,760)
Other expense		
Interest expense	3	4
Total other expense	3	4
Loss before income tax expense	(4,201)	(17,764)
Income tax expense	1	1
Net loss	(4,202)	(17,765)
Basic and diluted net loss per share	$ (0.60)	$ (2.35)
Basic and diluted weighted average common shares outstanding	6,951	7,545

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Stockholders' Deficit
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Deficit
Balances at December 31, 2015 (as previously reported)	6,739	$ 69	$ 5,827	$ (7,042)	$ (1,146)
Prior period error (Note 3)	49	(68)	68	(380)	(380)
Balances at December 31, 2015 (restated)	6,788	1	5,895	(7,422)	(1,526)
Common stock issued (restated)	658	—	5,265	—	5,265
Common stock issued for services	17	—	83	—	83
Net loss (restated)	—	—	—	(4,202)	(4,202)
Balances at December 31, 2016 (restated)	7,463	1	11,243	(11,624)	(380)
Common stock issued	421	—	10,430	—	10,430
Common stock issued for services	4	—	100	—	100
Net loss	—	—	—	(17,765)	(17,765)
Balances at December 31, 2017	7,888	$ 1	$ 21,773	$ (29,389)	$ (7,615)

See notes to financial statements.

Ra Medical Systems, Inc.

Statements of Cash Flows
(in thousands)

	Year ended December 31,	
	2016 (restated)	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,202)	$(17,765)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	95	218
Provision for doubtful accounts	12	—
Stock-based compensation	2,300	12,706
Common stock issued in exchange for services	42	100
Loss on disposal of property and equipment	—	53
Changes in operating assets and liabilities:		
Accounts receivable	(161)	(124)
Inventories	(181)	(644)
Prepaid expenses and other assets	(34)	(8)
Accounts payable	124	(47)
Accrued expenses	(103)	(95)
Deferred revenue	360	(91)
Other liabilities	(138)	174
Net cash used in operating activities	(1,886)	(5,523)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(210)	(547)
Net cash used in investing activities	(210)	(547)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	5,265	10,430
Proceeds from equipment financing	130	—
Payments on equipment financing	(22)	(44)
Net cash provided by financing activities	5,373	10,386
NET CHANGE IN CASH AND CASH EQUIVALENTS	3,277	4,316
CASH AND CASH EQUIVALENTS, beginning of year	644	3,921
CASH AND CASH EQUIVALENTS, end of year	$ 3,921	$ 8,237
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:		
Stock issued for software implementation services	$ 42	$ —
Transfer from inventories to property and equipment for demonstration lasers and lasers placed with customers	$ 93	$ 377
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 3	$ 4
Cash payments for taxes	$ 1	$ 1

See notes to financial statements.

Ra Medical Systems, Inc.

Notes to Financial Statements

Note 1—Organization and Nature of Operations

Ra Medical Systems, Inc. (the "Company") was formed in September 4, 2002, in the state of California and reincorporated in Delaware on July 14, 2018. The Company is a medical device company commercializing advanced excimer lasers for use in the treatment of dermatological and vascular diseases. The Company develops, manufactures and markets medical devices targeting the dermatology and vascular specialties. The Company's product development centers around proprietary applications of its excimer technology for use in the treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma and peripheral artery disease ("PAD").

Note 2—Significant Accounting Policies

Use of estimates—The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and reported disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. The Company's financial statements are based upon a number of estimates, including but not limited to, accounts receivable reserves, inventory reserves, reserves for warranty costs, fair value of stock option awards granted and revenue recognition for multiple element arrangements.

Cash and cash equivalents—The Company considers all short-term, highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents primarily represent funds invested in readily available checking and money market accounts.

Accounts receivable, net—Trade accounts receivable are presented net of allowances for doubtful accounts and other credits.

The Company sells or leases its lasers to distributors or physicians directly with various forms of financing options. The Company does business and extends credit based on an evaluation of the customers' financial condition generally without requiring collateral. Exposure to losses on trade receivables is expected to vary by customer due to the financial condition of each customer. The Company monitors exposure to credit losses and maintains allowances for anticipated losses considered necessary under the circumstances.

The Company maintains an allowance for doubtful accounts for balances that appear to have specific collection issues. The collection process is based on the age of the invoice and requires attempted contacts with the customer at specified intervals. If, after a specified number of days, the Company has been unsuccessful in its collection efforts, provision for doubtful accounts is recorded for the balance in question. Delinquent accounts receivable are charged against the allowance for doubtful accounts once the Company has determined the amounts are uncollectible. The factors considered in reaching this determination are the apparent financial condition of the customer and the Company's success in contacting and negotiating with the customer. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

The following table shows the allowance for doubtful accounts activity (in thousands):

	December 31,	
	2016	2017
Balanced at beginning of period	$—	$ 12
Provision for doubtful accounts	12	—
Write-offs	—	—
Balance at end of period	$ 12	$ 12

Inventories, net—Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Cost includes materials, labor and manufacturing overhead related to the purchase and production of inventories. The Company reduces the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technological developments or other economic factors.

Property and equipment, net—Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives as follows:

Computer hardware and software	4 years
Furniture and fixtures	5 years
Machinery and equipment	10 years
Demonstration lasers and lasers placed with customers	5 years
Automobiles	5 years

Leasehold improvements are depreciated over the shorter of the useful life of the leasehold improvement or the term of the underlying property's lease.

When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the account balances and any resulting gain or loss is recognized in income for the period. The cost of repairs and maintenance is expensed as incurred, whereas significant betterments are capitalized.

Impairment of long-lived assets—The Company periodically reviews its long-lived assets for impairment when certain events or changes in circumstances indicate that the carrying value of the long-lived assets may not be recoverable. Should the sum of the undiscounted expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. There were no impairment charges for the years ended December 31, 2016 or 2017.

Fair value of financial instruments—Cash and cash equivalents, trade accounts receivable, accounts payable, accrued expenses, deferred revenue and other current assets and liabilities are reported on the balance sheet at carrying value which approximates fair value due to the short-term maturities of these instruments.

The fair value of the Company's debt, which is classified as equipment financing liability on the balance sheets, is estimated based on current rates offered to the Company for similar debt and approximates carrying value.

Fair value measurements—Fair value represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants and is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier value hierarchy is used to identify inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Inputs other than the quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and

Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The Company's only assets or liabilities measured at fair value are its stock-based compensation liability and its abandoned operating lease. Note 11 and Note 13 discuss the valuation techniques for the stock-based compensation liability and abandoned operating lease, respectively.

Product warranty—The Company records estimated product warranty costs at the time of sale. Products are warrantied against defects in material and workmanship when properly used for their intended purpose and appropriately maintained. Product warranties are included for the first year after the sale. The product warranty liability is determined based on historical information such as past experience, product failure rates or number of units repaired, estimated cost of material and labor, and in certain instances, estimated property damage. The customer may purchase an extended service contract, which is either negotiated in the contract or sold as a separate component for which revenue is deferred over the term of the agreement.

The warranty accrual is included in accrued expenses in the accompanying balance sheets. Warranty expenses are included in cost of sales in the accompanying statements of operations. Changes in estimates to previously established warranty accruals result from current period updates to assumptions regarding repair costs and are included in current period warranty expense.

Revenue recognition

Product Sales

The Company recognizes revenues from the product sales when the following four criteria have been met: (i) the product has been shipped or services have been performed and the Company has no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of provisions for estimated expected returns and cash discounts.

None of the Company's sales contain right-of-return provisions and the Company has historically only experienced nominal returns. However, the Company estimates a provision for expected returns for the

catheter sales used in its DABRA laser system. The provision is based on the Company's best estimate of the number of products that will be returned as defective products based on the nature of the consumable. No provision is made for expected returns from other product sales, including the sales of devices, as the Company does not have a history of returns. If it becomes known that actual return rates deviate from the Company's original estimates, the provision for expected returns will be adjusted accordingly. The provision for expected returns is recorded as a reduction of accounts receivable and product sales.

The Company also offers certain cash discounts associated with the sales of its products. These discounts are negotiated on a transaction by transaction basis and therefore do not include any estimate at the time of sale. The discounts are recorded as a reduction to accounts receivable and product sales.

For shipment of its products, the Company takes into account the time at which to recognize revenue, generally this is when title and risk of loss is transferred.

Multiple Element Arrangements

The Company regularly enters into contracts where revenue is derived from multiple deliverables, including products or services. These contracts typically include an instrument and extended service contracts. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

Arrangement consideration is then allocated to those separate units of account based on their relative selling price. When applying the relative selling price method, the selling price for each deliverable is determined using the following hierarchy: (i) vendor-specific objective evidence ("VSOE") of the selling price; (ii) third-party evidence of selling price; or (iii) best estimated selling price. The Company records revenue related to these multiple deliverables as products are delivered and services are performed. In order to establish VSOE of selling price, the Company must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. In cases where there is not a sufficient number of standalone sales and VSOE of selling price cannot be determined, then the Company utilizes third-party evidence of selling price, if available, or best estimated selling price ("BESP").

The Company determines BESP for an individual element based on the average selling price of such discrete element during the annual period, excluding transactions that are not representative of standalone sales. The Company regularly reviews and maintains its BESP and updates these estimates at least annually.

Billable Service Arrangements

Revenue from billable services, including repair activity, is recognized when the service is provided.

Extended Warranty Arrangements

Revenues received with respect to extended warranties on products are recognized over the duration of the extended warranty period on a straight-line basis.

Lease Arrangements

The Company also derives revenue pursuant to product lease agreements. These leases are classified as operating leases in accordance with the relevant accounting guidelines, and the related revenue is recognized on a straight-line basis.

Distributor Transactions

In certain markets, the Company sells products and provides services to customers through distributors that specialize in medical device products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. These transactions are accounted for in accordance with the Company's revenue recognition policy described herein.

Shipping and handling costs—Shipping and handling charged to customers is included in net product sales. Shipping and handling costs are included in selling, general and administrative expenses in the accompanying statements of operations. Shipping and handling costs were $0.2 million and $0.3 million for the years ended December 31, 2016 and 2017, respectively.

Advertising expense—The Company charges advertising costs to expense as incurred. Advertising expense for the years ended December 31, 2016 and 2017, amounted to $7,500 and $23,000, respectively.

Research and development—Major components of research and development costs include personnel compensation expenses, stock-based compensation, consulting, materials and clinical trial expenses. Research and development expenses are charged to operations in the period they are incurred.

Patents—The Company expenses patent costs, including related legal costs, as incurred and records such costs within selling, general and administrative expense in the accompanying statements of operations.

Stock-based compensation—The Company evaluates whether an award should be classified and accounted for as a liability award or equity award for all stock-based compensation awards granted.

Stock-based compensation for liability awards issued to employees, directors, consultants, and other service providers is measured based on fair value of the award using the Black Scholes option pricing model. Changes in the fair value of a liability incurred under a share-based payment arrangement that occur during the requisite service period are recognized as compensation cost over that period. The percentage of the fair value that is accrued as compensation cost at the end of each period is equal to the percentage of the requisite service that has been rendered at that date. Any difference between the amount for which a liability award is settled and its fair value at the settlement date is recorded as an adjustment to compensation cost in the period of settlement.

Stock-based compensation expense for equity instruments issued to employees and directors is measured based on estimating the fair value of each stock option on the date of grant using the Black Scholes option pricing model. Equity instruments issued to nonemployee consultants and service providers are valued using the Black Scholes option pricing model and are subject to revaluation as the underlying equity instruments vest.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

As of December 31, 2016 and 2017, all stock-based compensation awards have been classified as liabilities in the financial statements. See Note 11.

The Company recognizes stock-based compensation expense as follows:

	Employees	Nonemployees
Service condition only	Straight-line	Re-value through the performance commitment date
Performance criterion is probable of being met:		
Service criterion is complete	Recognize the grant date fair value of the award once the performance criterion is considered probable of occurrence	Re-value the award once the performance criterion is considered probable of occurrence and recognize expense for the then fair value of the award
Service criterion is not complete	Straight-line	Straight-line, except the award is re-valued through the performance commitment date
Performance criterion is not probable of being met	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above	No expense is recognized until the performance criterion is considered probable, at which point expense is recognized per above

Income taxes—The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences reverse. Any resulting net deferred tax assets are evaluated for recoverability and, accordingly, a valuation allowance is provided when it is more likely than not that all or some portion of the deferred tax asset will not be realized.

The Company accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining whether it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. An uncertain tax position is considered effectively settled on completion of an examination by a taxing authority if certain other conditions are satisfied. Should the Company incur interest and penalties relating to tax uncertainties, such amounts would be classified as a component of interest expense and other expense, respectively.

Comprehensive loss—Comprehensive loss is equal to net loss for all periods presented.

Concentrations of credit risk—Credit risk represents the accounting loss that would be recognized at the reporting date if counterparties failed completely to perform as contracted. Concentrations of credit risk that arise from financial instruments exist for groups of customers or counterparties when they have similar economic characteristics that would cause their ability to meet contractual obligations to be similarly affected by changes in economic or other conditions described below.

Financial instruments, which potentially subject the Company to concentration of credit risk, consist of cash balances maintained in excess of Federal Depository Insurance Corporation limits, and accounts receivable which have no collateral or security. The Company monitors the financial condition of the banks in which it currently has deposits. The Company has not experienced any significant losses in this respect and believes that it is not exposed to any significant related risk.

Exposure to losses on accounts receivable is dependent on the individual customer's financial condition. The Company monitors its exposure to credit losses and reserves for those accounts receivable that it deems to be not collectible.

As of December 31, 2016, accounts receivable due from two of the Company's customers was 37%, and as of December 31, 2017, accounts receivable due from four of the Company's customers was 57% of accounts receivable.

No individual customer represented greater than 10% of total net revenue for the years ended December 31, 2016 or 2017.

Recent accounting pronouncements—On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the "JOBS Act") into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies, which are the dates included below.

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for fiscal years ending after December 15, 2016. The Company adopted ASU 2014-15 effective January 1, 2017. The impact on the financial statements and related disclosures was not material.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, ("ASU 2015-11"). The update requires that for entities that measure inventory using the first-in, first-out method, inventory should be measured at the lower of cost and net realizable value. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The update is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company early adopted ASU 2015-11 effective January 1, 2017. The impact on the financial statements and related disclosures was not material.

In March 2016, FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*. The ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2017, with early adoption permitted. The Company early adopted ASU 2016-09 effective January 1, 2017. The impact on these financial statements and related disclosures was not material.

In May 2014, FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and issued subsequent amendments to the initial guidance in August 2015, March 2016, April 2016 and May 2016 within ASU 2015-14, ASU 2016-08, ASU 2016-10 and ASU 2016-12, respectively. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles in the United States ("US GAAP"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle, and in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing US GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation, among others. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2018 with (i) retrospective application of ASU 2014-09 to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09 or (ii) retrospective application of ASU 2014-09 with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. The Company does not believe adoption of this guidance will have a material impact on revenue recognition, but it will require additional disclosures.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). This update requires lessees to recognize on the balance sheet a lease liability and a lease asset for all leases with a term greater than 12 months, including operating leases. The update also expands the required quantitative and qualitative disclosures surrounding leases. Under the new standard, the Company will have to recognize a liability representing its lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet. ASU 2016-02 is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is evaluating the effect that this guidance will have on the financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. Under the ASU, an entity will account for the effects of a modification unless (i) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified, (ii) the vesting conditions of the modified award are the same vesting conditions as the original award immediately before the original award is modified and (iii) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments in this ASU are effective prospectively for fiscal years, and interim periods within those annual periods, beginning after December 15, 2017. This adoption of this ASU is not expected to have a material impact on the Company's financial statements or related disclosures.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Note 3—Restatement and reclassifications

Subsequent to the issuance of the Company's financial statements as of and for the year ended December 31, 2016, which statements have been reaudited, management identified certain errors consisting of:

- The Company determined that stock option awards that were communicated to employees, directors, consultants and service providers (together the "Optionees") were not validly authorized. Although the communicated awards are not outstanding options, the Company believes the communicated awards represent a contractual obligation to the Optionees. As a result, the awards are required to be classified as liabilities remeasured at each reporting date, rather than as equity-classified option awards as previously reported. This resulted in an understatement of the total stock-based compensation expense of $2.0 million in 2016, the reversal of stock-based compensation expense previously recorded to additional paid-in capital of $0.3 million, and a cumulative adjustment to beginning accumulated deficit of $0.3 million.
- Deferred rental income of $0.1 million as of December 31, 2016, previously included as a component of accrued expenses rather than as a component of deferred revenue, current portion.
- A misstatement of $0.1 million of the total amount of depreciation and amortization expense included on the statement of cash flows in 2016. The amounts presented for total cash used operating activities on the statement of operations were correct.
- Other miscellaneous items related to accounts receivable, deferred revenue, accrued expenses, common stock, product sales and cost of sales.
- There were corresponding misstatements in the statement of cash flows for the above matters.

As a result of these errors, the Company has restated the accompanying 2016 financial statements.

The Company also made certain reclassifications of amounts previously presented to conform to the current period. Such reclassifications on the balance sheet include $0.1 million of demonstration laser devices previously included in inventory to property and equipment, net. Such reclassifications on the statement of operations include changes in presentation of net revenues to separately present product sales and service and other revenues separately to conform to the United States Securities and Exchange Commission requirements. There were other miscellaneous reclassifications made between line items for customer deposits, shipping and handling amounts charged to customers and interest expense on corporate credit card balances. There were corresponding impacts to the statement of cash flows.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

The following is a summary of the impact of the restatement and reclassifications on the Company's balance sheet (in thousands):

	December 31, 2016			
	As Previously Reported	Correction of Errors	Reclassifications	As Restated
Accounts receivable, net	$ 405	$ (12)	$ —	$ 393
Inventories, net	964	(1)	(93)	870
Total current assets	5,414	(13)	(93)	5,308
Property and equipment, net	413	—	93	506
Total assets	5,855	(13)	—	5,842
Accrued expenses	591	(162)	(10)	419
Current portion of deferred revenue	1,620	124	—	1,744
Other current liabilities	22	—	10	32
Total current liabilities	2,748	(38)	—	2,710
Deferred revenue	804	32	—	836
Stock-compensation liability	—	2,611	—	2,611
Total liabilities	3,617	2,605	—	6,222
Common stock	76	(75)	—	1
Additional paid-in capital	11,495	(252)	—	11,243
Accumulated deficit	(9,333)	(2,291)	—	(11,624)
Total stockholders' equity (deficit)	2,238	(2,618)	—	(380)
Total liabilities and stockholders' equity (deficit)	$ 5,855	$ (13)	$ —	$ 5,842

The following is a summary of the impact of the restatement and reclassifications on the Company's statement of operations (in thousands):

	Year ended December 31, 2016			
	As Previously Reported	Correction of Errors	Reclassifications	As Restated
Product sales	$ —	$ (5)	$ 3,822	$ 3,817
Service and other	—	—	2,159	2,159
Total net revenue	5,937	(5)	44	5,976
Product	—	87	2,202	2,289
Service and other	—	(19)	868	849
Total cost of sales	3,070	68	—	3,138
Gross profit	2,867	(73)	44	2,838
Selling, general and administrative	4,335	924	62	5,321
Research and development	801	914	—	1,715
Total operating expenses	5,136	1,838	62	7,036
Operating loss	(2,269)	(1,911)	(18)	(4,198)
Interest expense	21	—	(18)	3
Loss before income tax	(2,290)	(1,911)	—	(4,201)
Net loss	$ (2,291)	$ (1,911)	$ —	$ (4,202)

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

The following is a summary of the impact of the restatement and reclassifications on the Company's statement of cash flows (in thousands):

	Year ended December 31, 2016			
	As Previously Reported	Correction of Errors	Reclassifications	As Restated
Net loss	$ (2,291)	$ (1,911)	$ —	$ (4,202)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	5	90	—	95
Provision for doubtful accounts	—	12	—	12
Stock-based compensation	325	1,975	—	2,300
Changes in operating assets and liabilities:				
Inventories	(156)	(25)	—	(181)
Accrued expenses	(62)	(165)	124	(103)
Deferred revenue	246	114	—	360
Other liabilities	(14)	—	(124)	(138)
Supplemental disclosure of non-cash investing activities:				
Transfer from inventories to property and equipment for demonstration lasers and lasers placed with customers	—	—	93	93
Supplemental cash flow information:				
Interest	$ 21	$ —	$ (18)	$ 3

The restatement had no net effect on cash flows from operations, investing or financing. The restatement also had a beginning adjustment to accumulated deficit of $0.4 million, of which $0.3 million and $0.1 million related to stock compensation and the other insignificant errors described above, respectively.

Note 4—Inventories, net

Inventories consisted of the following (in thousands):

	December 31	
	2016	2017
Raw materials	$449	$ 705
Work in process	18	110
Finished goods	403	381
Inventories, net	$870	$1,196

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Note 5—Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	December 31, 2016	December 31, 2017
Computer hardware and software	$ 122	$ 301
Furniture and fixtures	41	60
Machinery and equipment	606	745
Demonstration lasers and lasers placed with customers	106	483
Automobiles	85	154
Leasehold improvements	28	13
Construction in progress	107	178
	1,095	1,934
Accumulated depreciation	(589)	(775)
Property and equipment, net	$ 506	$1,159

Depreciation expense was $0.1 million and $0.2 million for the years ended December 31, 2016 and 2017, respectively.

Note 6—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2016	December 31, 2017
Compensation and related benefits	$154	$ 236
Accrued warranty (Note 7)	97	87
Other accrued expenses	168	1
Accrued expenses	$419	$ 324

Note 7—Accrued Warranty

Activity in the product warranty accrual is included in accrued expenses above and consists of the following (in thousands):

	December 31, 2016	December 31, 2017
Balanced at beginning of period	$ 112	$ 97
Increase in warranty accrual	207	198
Claims satisfied	(222)	(208)
Accrued warranty	$ 97	$ 87

Warranty expense was $0.2 million for each of the years ended December 31, 2016 and 2017, respectively, and is included in service and other cost of revenue in the accompanying statements of operations.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Note 8—Long-Term Debt and Equipment Financing

The Company had a line of credit with a bank allowing for borrowing up to $0.3 million, collateralized by personal property of the Company and guaranteed by a shareholder of the Company, with interest at 4.5% per year. There were no balances outstanding on the Company's line of credit as of December 31, 2016. The line of credit expired on September 1, 2017.

During 2016, the Company entered into two loan agreements to finance equipment placed in physician's offices under monthly rental contracts. Interest expense for the years ended December 31, 2016 and 2017 associated with these transactions was $3,000 and $4,000, respectively.

Future maturities are as follows (in thousands):

Years ending December 31,	
2018	$44
2019	19
Total	$63

Note 9—Stockholders' Deficit

Common stock—The Company has one class of stock: common shares. The Company issued 658,125 and 421,450 shares of stock in exchange for $5.3 million and $10.4 million that related to the private placements which took place in 2016 and 2017, respectively.

Common stock issued for services—During 2016 and 2017, the Company paid certain accounting and consulting services with Company stock. In 2016, the Company issued 16,649 shares valued at $0.1 million of which $42,000 was capitalized as part of the implementation of the Company's enterprise resource planning system and $42,000 was expensed as accounting services during the year and included as a component of selling, general and administrative on the statement of operations. In 2017, the Company issued 4,000 shares as payment for $0.1 million of consulting services performed and included as a component of selling, general and administrative on the statement of operations.

The number of shares issued was based on the fair value of the common stock at the date of the performance of the accounting and consulting services and the associated to amount owed by the Company in exchange for such services. See Note 11 for further discussion on the valuation techniques used for the Company's common stock.

Note 10—Loss per Share

The Company calculates basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per share would reflect the effects of potentially dilutive securities, if any. For the years ended December 31, 2016 and 2017, basic and diluted loss per share were the same.

Note 11—Stock-Based Compensation

In 2003, the Company adopted a stock option plan, which authorized the board of directors to grant stock option awards to eligible Optionees of the Company. In April 2012, such plan expired. In 2014, the Company established the 2014 Stock Option Plan (the "2014 Plan") whereby 1,000,000 shares of

the Company's common stock were reserved for issuance to eligible Optionees. The 2014 Plan provided for the grant of incentive stock options, non-statutory stock options, stock bonuses and rights to acquire restricted stock. Option awards under the 2014 Plan expired up to a maximum of 10 years from the date of the grant. On May 17, 2018, the Company's board of directors terminated the 2014 Plan.

As described in Note 3, the Company has concluded that option awards communicated to Optionees were not validly authorized. Although the communicated awards are not outstanding options, the Company believes the communicated awards represent a contractual obligation to the Optionees, and the Company has classified the option awards as liabilities in the financial statements.

Obligations under the Plans include time and performance-based awards. For time-based awards, vesting generally occurs over the service period of up to four years. Performance based awards vest at the time that the underlying performance conditions are met.

The liabilities for stock-based compensation awards have been classified as a component of noncurrent liabilities on the balance sheet as the Company does not expect that such amounts will be settled through the use of current assets or through the creation of current liabilities.

A summary of the activity and related information of the awards classified as liabilities and communicated during the year ended December 31, 2017, is presented below:

	Awards	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2016	654,500	$ 2.22	5.05	$ 3,781
Granted	394,000	7.35	6.02	
Forfeited	(115,000)	6.00	—	
Outstanding at December 31, 2017	933,500	$ 3.92	4.86	$ 19,676
Exercisable at December 31, 2017	641,000	$ 3.13	4.02	$ 14,019
Vested and expected to vest at December 31, 2017	933,500	$ 3.92	4.86	$ 19,676

No awards expired during the year ended December 31, 2017. There were no stock awards exercised in 2016.

Stock-based compensation expense recorded in operating expenses was as follows (in thousands):

	Year ended December 31,	
	2016	2017
Selling, general and administrative	$1,320	$ 8,744
Research and development	914	3,258
Stock-based compensation in operating expenses	$2,234	$ 12,022

Stock-based compensation amounts of $0.1 million and $0.7 million were capitalized to inventory during the years ended December 31, 2016 and 2017, respectively.

These awards are presented as a stock-based compensation liability which is revalued at each reporting period with the change in fair value recorded to compensation expense. As of December 31, 2016 and 2017, the stock-based compensation liability was $2.6 million and $15.4 million, respectively. The fair value of the stock-based compensation liability was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted in the following table:

	Year ended December 31,	
	2016	2017
Risk-free interest rate	1.45%	1.96%
Volatility	45.35%	43.70%
Expected dividend yield	0.00%	0.00%
Expected life	2.9	2.6

The weighted average fair value for awards granted during 2016 and 2017 is $5.97 and $21.52, respectively. The Company's shares are not traded in any public market. The common stock value as of the date of grant was based on the share price of recent equity issuances, if available. If there were no such recent transactions, the Company's share valuation was estimated using both the income and market approaches, which were weighted 50% each. A discount of 35% was then applied for lack of marketability for the Company's common stock. As of December 31, 2016 and 2017, the dates at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with new third party investors who were not previous shareholders of the Company. The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period. During 2016, the Company early adopted ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which among other things, allows the Company to account for forfeitures as they occur.

Note 12—Income Taxes

A reconciliation of the differences between the United States statutory federal income tax rate and the effective tax rate as provided in the statement of operations is as follows:

	Year ended December 31,	
	2016	2017
Tax computed at the federal statutory rate	34.0%	34.0%
State income taxes, net of federal benefits	5.0	5.8
Tax reform—tax rate change	—	(18.6)
Other	4.4	(0.0)
Change in valuation allowance	(34.6)	(21.2)
	(0.0%)	(0.0%)

The federal and state income tax provision is summarized as follows:

	Year ended December 31,	
	2016	2017
Current		
Federal	$ —	$ —
State	1	1
	1	1
Deferred		
Federal	—	—
State	—	—
	—	—
Income tax expense	$ 1	$ 1

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes, and (b) operating losses and tax credit carryforwards.

The tax effects of significant components of the Company's deferred tax assets (liabilities) are as follows:

	December 31,	
	2016	2017
Deferred Tax Assets:		
Net operating loss carryforwards	$ 1,123	$ 1,994
Other accruals	16	79
Reserves	165	142
Deferred revenue	1,028	697
Capitalized research and development	684	618
Stock-based compensation liability	1,040	4,314
	4,056	7,844
Deferred Tax Liabilities:		
Property and equipment	(1)	(5)
Valuation allowance	(4,055)	(7,839)
Total deferred taxes	$ —	$ —

At December 31, 2017, the Company had available federal and state net operating loss carryforwards of approximately $7.2 million and $7.0 million, respectively, which may be used to offset future federal and state taxable earnings. The federal and state net operating losses begin expiring in 2029. Use of these net operating loss carryforwards may be significantly limited under the tax rules regarding the use of losses following an ownership change under Internal Revenue Code ("IRC") Section 382. The Company has not completed an IRC Section 382 analysis regarding the limitation of net operating losses.

ASC 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is

"more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is not currently more likely than not to be realized and, accordingly, has provided a full valuation allowance at December 31, 2016 and 2017.

The difference between the statutory federal income tax rate and the effective income tax rate reported in the statements of operations is primarily due to the Tax Act (as defined below), state income taxes and the change in the valuation allowance.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is no longer subject to audit by U.S. federal, state and local tax authorities for years before 2013. The Company is not currently under examination by any taxing jurisdiction. As of December 31, 2016 and 2017, there is no accrued interest or penalties recorded in the financial statements. However, the net operating loss carryover may be adjusted three years from the date the loss is utilized on an income tax return.

On December 22, 2017, the President of the United States signed into law the Tax Reform Act (the "Tax Act"). The Tax Act significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, eliminating certain deductions, allowing full expensing of capital spending, implementing a territorial tax system, and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. The Company has completed its analysis of the Tax Act. The Tax Act permanently reduces the U.S. corporate income tax rate from a maximum of 34% to a flat 21% rate, effective January 1, 2018. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the Tax Act, the Company revalued its ending net deferred tax assets at December 31, 2017. The impact of this revaluation was offset by a reduction in the valuation allowance, thus having no impact on the income tax expense recognized in the statement of operations for the year ended December 31, 2017

Note 13—Commitments and Contingencies

Capital stock transactions—The Company has determined that there have been defects with respect to certain capital stock transactions, including stock issuances and a reverse stock split, which were not effected in accordance with the requirements of applicable law. The Company could be subject to claims based on the defects. The Company believes any loss as a result of such defects is remote.

Legal—In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

Lease commitments—The Company has various noncancelable operating leases related to office spaces and manufacturing facilities in Carlsbad, California. In 2017, the Company entered into a new operating lease for office space and manufacturing facilities and abandoned its old leases. The Company recorded an expense and a corresponding liability of $0.2 million as a result of the lease abandonment, which represents the fair value of the lease termination costs upon initial measurement. The liability includes the estimated costs, net of estimated subleasing proceeds, the Company expects to incur during the lease term using the credit-adjusted risk-free interest rate. The initial expense is included in selling, general and administrative expenses in the accompanying statement of operations. The initial liability measured at fair value is included in accrued expenses and other liabilities on the accompanying balance sheet as of

December 31, 2017. In periods subsequent to initial measurement, changes to the liability will be measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

Some of these agreements have escalating rent payment provisions. Rent expense under such agreements is recognized on a straight-line basis. Total rent expense for the years ended December 31, 2016 and 2017, was $0.2 million and $0.3 million, respectively.

Future minimum rental payments due are as follows (in thousands):

Years ending December 31,	
2018	$ 517
2019	500
2020	514
2021	529
2022	432
Thereafter	2,363
Total	$ 4,855

Note 14—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the dermatology segment and the vascular segment.

In deciding how to allocate resources and assess performance, the Company's chief operating decision maker regularly evaluates the sales and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to the Company and not specific to a particular segment; therefore, these amounts are not evaluated by the Company's chief operating decision maker on a segmented basis.

The following tables summarize segment performance for the years ended December 31, 2016 and 2017 (in thousands):

	Year ended December 31,	
	2016	2017
Vascular	$ —	$ 259
Dermatology	5,976	5,611
Net revenue	$5,976	$5,870
Vascular	$ —	$ 193
Dermatology	3,138	3,972
Cost of revenue	$3,138	$4,165
Vascular	$ —	$ 66
Dermatology	2,838	1,639
Gross profit	$2,838	$1,705

Generally, all assets are common assets, except for demonstration lasers and lasers placed with customers, which are a subset of property and equipment. Demonstration lasers and lasers placed with customers aggregated in the vascular segment was $12,000 and $0.2 million as of December 31, 2016 and 2017, respectively. Demonstration lasers and lasers placed with customers aggregated in the dermatology segment was $0.1 million and $0.3 million as of December 31, 2016 and 2017, respectively.

No sales to an individual customer or country other than the United States accounted for more than 10% of fiscal year 2016 or 2017 net revenue. Net revenue, classified by the major geographic areas in which our customers are located, was as follows:

	Year ended December 31,	
	2016	2017
United States	$5,735	$5,273
All other countries	241	597
Net revenue	$5,976	$5,870

Note 15—Subsequent Events

The Company has evaluated subsequent events through May 18, 2018, the date these financial statements were issued, and, with respect to the reincorporation in Delaware described below, through August 24, 2018.

Private Placement Financing—From January 2018 through May 2018, the Company issued 316,080 shares of common stock at a per share price of $25 for aggregate proceeds of $7.9 million in connection with a private placement financing.

Ra Medical Systems, Inc.

Notes to Financial Statements—(Continued)

Reincorporation in Delaware

On July 14, 2018, the Company reincorporated in Delaware and established the par value of each share of common stock to be $0.0001. In addition, the number of authorized shares of common stock was increased to 25,000,000. In connection with the reincorporation, common stock and additional paid-in capital amounts in these financial statements have been adjusted to reflect the par value of common stock. All share information included in these financial statements has been adjusted to reflect this reincorporation.

Ra Medical Systems, Inc

Condensed Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	December 31, 2017	June 30, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,237	$ 9,769
Accounts receivable, net	517	761
Inventories, net	1,196	1,258
Prepaid expenses and other current assets	92	267
Total current assets	10,042	12,055
Property and equipment, net	1,159	2,257
Other non-current assets	68	2,293
TOTAL ASSETS	$ 11,269	$ 16,605
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	$ 426	$ 2,436
Accrued expenses	324	1,673
Current portion of deferred revenue	1,714	1,718
Current portion of equipment financing	44	38
Other current liabilities	125	81
Total current liabilities	2,633	5,946
Deferred revenue	775	789
Equipment financing	19	4
Stock-based compensation liability	15,376	—
Other liabilities	81	88
Total liabilities	18,884	6,827
Commitments and contingencies (Note 10)		
Stockholders' (Deficit) Equity		
Common stock, $0.0001 par value, 25,000,000 shares authorized; 7,888,170 and 8,204,251 issued and outstanding, respectively	1	1
Additional paid-in capital	21,773	50,254
Accumulated deficit	(29,389)	(40,477)
Total stockholders' (deficit) equity	(7,615)	9,778
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 11,269	$ 16,605

See notes to condensed financial statements.

Ra Medical Systems, Inc

Condensed Statements of Operations (Unaudited)
(in thousands, except per share data)

	Six months ended June 30,	
	2017	2018
Net revenue		
Product sales	$ 1,301	$ 710
Service and other	1,342	1,495
Total net revenue	2,643	2,205
Cost of revenue		
Product sales	1,174	989
Service and other	639	737
Total cost of revenue	1,813	1,726
Gross profit	830	479
Operating expenses		
Selling, general and administrative	10,028	10,254
Research and development	3,746	1,308
Total operating expenses	13,774	11,562
Operating loss	(12,944)	(11,083)
Other expense		
Interest expense	2	2
Total other expense	2	2
Loss before income tax expense	(12,946)	(11,085)
Income tax expense	1	3
Net loss	(12,947)	(11,088)
Basic and diluted net loss per share	$ (1.73)	$ (1.38)
Basic and diluted weighted average common shares outstanding	7,464	8,020

See notes to condensed financial statements.

Ra Medical Systems, Inc

Condensed Statement of Stockholders' (Deficit) Equity (Unaudited)
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balances at December 31, 2017	7,888	$ 1	$ 21,773	$ (29,389)	$ (7,615)
Common stock issued	316	—	7,901	—	7,901
Settlement of stock-based compensation liability	—	—	18,243	—	18,243
Forfeitures of liability-classified awards			1,313		1,313
Stock-based compensation	—	—	1,024	—	1,024
Net loss	—	—	—	(11,088)	(11,088)
Balances at June 30, 2018	8,204	$ 1	$ 50,254	$ (40,477)	$ 9,778

See notes to condensed financial statements.

Ra Medical Systems, Inc

Condensed Statements of Cash Flows (Unaudited)
(in thousands)

	Six months ended June 30,	
	2017	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,947)	$ (11,088)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	86	231
Provision for doubtful accounts	—	88
Stock-based compensation	10,884	5,204
Changes in operating assets and liabilities:		
Accounts receivable	47	(332)
Inventories	(737)	(1,140)
Prepaid expenses and other assets	44	(165)
Accounts payable	218	760
Accrued expenses	(133)	495
Deferred revenue	(233)	18
Other liabilities	—	(37)
Net cash used in operating activities	(2,771)	(5,966)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(241)	(251)
Net cash used in investing activities	(241)	(251)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	50	7,901
Payments on equipment financing	(22)	(21)
Initial public offering costs	—	(131)
Net cash provided by financing activities	28	7,749
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,984)	1,532
CASH AND CASH EQUIVALENTS, beginning of period	3,921	8,237
CASH AND CASH EQUIVALENTS, end of period	$ 937	$ 9,769
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:		
Settlement of stock-based compensation liability	$ —	$ 18,243
Forfeitures of liability-classified awards	$ —	$ 1,313
Deferred initial public offering costs in accounts payable and accrued expenses	$ —	$ 2,104
Transfer from inventories to property and equipment for demonstration lasers and lasers placed with customers	$ 185	$ 1,078
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 1	$ 1

See notes to condensed financial statements.

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)

Note 1—Organization and Nature of Operations

Ra Medical Systems, Inc. (the "Company") was formed in September 4, 2002, in the state of California and reincorporated in Delaware on July 14, 2018. The Company is a medical device company commercializing advanced excimer lasers for use in the treatment of dermatological and vascular diseases. The Company develops, manufactures and markets medical devices targeting the dermatology and vascular specialties. The Company's product development centers around proprietary applications of its excimer technology for use in the treatment of psoriasis, vitiligo, atopic dermatitis, leukoderma, and peripheral artery disease ("PAD").

Note 2—Significant Accounting Policies

Interim condensed financial information—The interim condensed financial statements as of June 30, 2018 and for six months ended June 30, 2017 and 2018 are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed financial position as of June 30, 2018 and its results of operations and cash flows for the six months ended June 30, 2017 and 2018. The financial data and other information disclosed in these notes to financial statements related to the six-month periods are also unaudited. The results of operations for the six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The balance sheet as of December 31, 2017 included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company's audited financial statements included elsewhere in this prospectus.

Use of estimates—The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and reported disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. The Company's financial statements are based upon a number of estimates, including but not limited to, accounts receivable reserves, inventory reserves, reserves for warranty costs, fair value of stock option awards granted and revenue recognition for multiple element arrangements.

Deferred Initial Public Offering Costs—The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings until such financings are consummated. Deferred initial public offering ("IPO") costs of $2.2 million are capitalized and included within Other non-current assets on the condensed balance sheet as of June 30, 2018. There were no deferred IPO costs as of December 31, 2017. The deferred IPO costs will be offset against any proceeds from the IPO upon its consummation as a reduction of stockholders' deficit. In the event the IPO is terminated or abandoned, all capitalized deferred IPO costs will be expensed within selling, general and administrative expenses.

Recent accounting pronouncements—On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the "JOBS Act") into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on

which adoption of such standards is required for non-public companies, which are the dates included below.

In May 2014, FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and issued subsequent amendments to the initial guidance in August 2015, March 2016, April 2016 and May 2016 within ASU 2015-14, ASU 2016-08, ASU 2016-10 and ASU 2016-12, respectively. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles in the United States ("US GAAP"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle, and in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing US GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation, among others. The new standard also requires an entity to recognize as an asset the incremental costs of obtaining a contract with a customer if the entity expects to recover those costs. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2018, and interim reporting periods within annual reporting periods beginning after December 15, 2019, with (i) retrospective application of ASU 2014-09 to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09 or (ii) retrospective application of ASU 2014-09 with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09 (the modified retrospective method).

While the Company has not completed its evaluation, the Company currently plans to adopt this accounting standard in the first quarter of fiscal year 2019 using the modified retrospective method. Based on the analysis performed through the second quarter of 2018, the Company does not believe adoption of this guidance will have a material impact on the timing and measurement of revenue under its contracts with customers, but it will require additional disclosures.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). This update requires lessees to recognize on the balance sheet a lease liability and a lease asset for all leases with a term greater than 12 months, including operating leases. The update also expands the required quantitative and qualitative disclosures surrounding leases. Under the new standard, the Company will have to recognize a liability representing its lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet. ASU 2016-02 is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted.

Lessor accounting under ASU 2016-02 is similar to the current model but updated to align with certain changes to the lessee model. Lessors will continue to classify leases as operating, direct financing or sales-type leases. In addition, the new standard requires that lease and nonlease components of a contract be bifurcated, with nonlease components subject to the new revenue recognition standard effective upon adoption of the new leasing standard. In January 2018, the FASB issued a proposed amendment that, if adopted by the FASB, would allow lessors to elect to account for the lease and nonlease components as a single combined lease component if (i) the timing and pattern of the revenue recognition is the same, and (ii) the combined lease component would continue to be classified as an operating lease. The Company is evaluating the effect that this guidance will have on the financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. Under the ASU, an entity will account for the effects of a modification unless (i) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified, (ii) the vesting conditions of the modified award are the same vesting conditions as the original award immediately before the original award is modified and (iii) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments in this ASU are effective prospectively for fiscal years, and interim periods within those annual periods, beginning after December 15, 2017. The Company adopted ASU 2017-09 on January 1, 2018 and the adoption did not have a material impact on the Company's financial statements or related financial statement disclosure.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. ASU 2018-07 expands the scope of Topic 718, *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, *Revenue from Contracts with Customers*. The Company is evaluating the effect that this guidance will have on the financial statements and related disclosures.

Note 3—Inventories, net

Inventories consisted of the following (in thousands):

	December 31, 2017	June 30, 2018
Raw materials	$ 705	$ 906
Work in process	110	112
Finished goods	381	240
Inventories, net	$ 1,196	$ 1,258

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

Note 4—Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	December 31, 2017	June 30, 2018
Computer hardware and software	$ 301	$ 346
Furniture and fixtures	60	66
Machinery and equipment	745	980
Demonstration lasers and lasers placed with customers	483	1,560
Automobiles	154	200
Leasehold improvements	13	79
Construction in progress	178	23
Property and equipment, gross	1,934	3,254
Accumulated depreciation	(775)	(997)
Property and equipment, net	$ 1,159	$ 2,257

Depreciation expense was $0.1 million and $0.2 million for the six months ended June 30, 2017 and 2018, respectively.

Note 5—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2017	June 30, 2018
Compensation and related benefits	$ 236	$ 530
Accrued warranty (Note 6)	87	52
Accrued IPO costs	—	854
Other accrued expenses	1	237
Accrued expenses	$ 324	$ 1,673

Note 6—Accrued Warranty

Activity in the product warranty accrual is included in accrued expenses above and consists of the following (in thousands):

	December 31, 2017	June 30, 2018
Balanced at beginning of period	$ 97	$ 87
Increase in warranty accrual	198	45
Claims satisfied	(208)	(80)
Accrued warranty	$ 87	$ 52

Warranty expense was $0.1 million for each of the six months ended June 30, 2017 and 2018, respectively, and is included in service and other cost of revenue in the accompanying statements of operations.

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

Note 7—Stockholders' Deficit

Common stock—The Company has one class of stock: common shares. The Company issued 316,080 shares of common stock in exchange for $7.9 million that related to the private placements which took place during the six months ended June 30, 2018.

Note 8—Loss per Share

The Company calculates basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per share would reflect the effects of potentially dilutive securities, if any. For each of the six months ended June 30, 2017 and 2018, basic and diluted loss per share were the same.

Note 9—Stock-Based Compensation

In 2003, the Company adopted a stock option plan (the "2003 Plan"), which authorized the board of directors to grant stock option awards to eligible employees, directors, consultants and service providers (together the "Optionees") of the Company. In April 2012, such plan expired. In 2014, the Company established the 2014 Stock Option Plan (the "2014 Plan") whereby 1,000,000 shares of the Company's common stock were reserved for issuance to eligible Optionees. The 2014 Plan provided for the grant of incentive stock options, non-statutory stock options, stock bonuses and rights to acquire restricted stock. Option awards under the 2014 Plan expired up to a maximum of 10 years from the date of the grant.

The Company concluded that option awards communicated to Optionees (the "Communicated Option Awards") were not validly authorized. Although the Communicated Option Awards were not outstanding options, the Company believes the awards represented a contractual obligation to the Optionees and therefore the Company classified the option awards as liabilities in the financial statements.

Obligations under the 2003 Plan and 2014 Plan included time and performance-based awards. For time-based awards, vesting generally occurred over the service period of up to four years. Performance based awards vested at the time that the underlying performance conditions were met.

The liabilities for stock-based compensation awards were classified as a component of noncurrent liabilities on the balance sheet as the Company did not expect that such amounts will be settled through the use of current assets or through the creation of current liabilities.

On May 17, 2018, the Company's board of directors terminated the 2014 Stock Option Plan and on June 4, 2018, it was replaced with the 2018 Stock Compensation Plan (the "2018 Plan") whereby 3,300,000 shares of the Company's common stock were reserved for issuance. The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock and restricted stock units. On June 4, 2018, the Company's board of directors authorized 1,901,900 replacement equity awards of stock options and, on June 8, 2018, 1,340,832 restricted stock units (collectively, the "Replacement Awards") to the Optionees. On various dates in June 2018, but after the board of directors' authorization, the Replacement Awards were communicated to the Optionees in exchange for the cancellation of, and waiver to any claims related to, the Communicated Option Awards granted under the 2003 Plan and 2014 Plan which were determined to be not validly authorized. The issuance of the Replacement Awards and cancellation of the Communicated Option Awards was treated as a modification. The modification date is the date of the grant of the Replacement Awards, such date being June 4, 2018, for options and June 8, 2018, for restricted stock unit awards. The Company will recognize the remaining unrecognized compensation cost, as well as any

incremental compensation cost of the Replacement Awards of $17.2 million, over the remaining service period of the Replacement Awards, as described below. As the Replacement Awards have been determined to be equity-classified awards, the Company will no longer record such awards as liabilities which are remeasured at fair value each reporting period.

Stock options granted under the 2018 Plan, including those granted as a component of the Replacement Awards, generally vest 33% at the first anniversary of the grant date with the balance vesting monthly over the remaining two years. The restricted stock units granted under the 2018 Plan, including those granted as a component of the Replacement Awards, include a service condition and a performance condition. The service condition generally begins on the grant date and continues through November 2019 and the restricted stock units vest at various times commencing the day following the expiration of the lock-up until November 2019. The performance condition relates to the Company completing its IPO and the vesting of the restricted stock units are contingent upon the achievement of such IPO.

A summary of the activity and related information of the Communicated Option Awards classified as liabilities and communicated during the six months ended June 30, 2018, is presented below:

	Liability-Classified Awards	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	933,500	$ 3.92	3.57	$ 19,676
Granted	170,000	25.00		
Forfeited	(67,000)	5.33		
Cancelled and settled with Replacement Awards	(1,036,500)	7.29		22,442
Outstanding at June 30, 2018	—	$ —	—	$ —
Exercisable at June 30, 2018	—	$ —	—	$ —
Vested and expected to vest at June 30, 2018	—	$ —	—	$ —

A summary of the activity and related information of the stock options issued during the six months ended June 30, 2018 is presented below:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	—	$ —	—	$ —
Granted	1,901,900	28.94		
Forfeited	(3,900)	28.94		
Outstanding at June 30, 2018	1,898,000	$ 28.94	9.9	$ —
Exercisable at June 30, 2018	—	$ —	—	$ —
Vested and expected to vest at June 30, 2018	1,898,000	$ 28.94	9.9	$ —

A summary of the activity and related information of the restricted stock units issued during the six months ended June 30, 2018 is presented below:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2017	—	$ —
Granted	1,340,832	28.94
Forfeited	(531)	28.94
Outstanding at June 30, 2018	1,340,301	$ 28.94

Stock-based compensation expense recorded in operating expenses was as follows (in thousands):

	Six months ended June 30,	
	2017	2018
Selling, general and administrative	$ 7,168	$ 3,958
Research and development	3,104	909
Stock-based compensation in operating expenses	$ 10,272	$ 4,867

Stock-based compensation amounts of $0.6 million and $0.3 million were capitalized to inventory during the six months ended June 30, 2017 and 2018, respectively.

Unrecognized compensation expense for stock options issued as of June 30, 2018 was $17.2 million and is expected to be recognized over a weighted-average period of 2.9 years. Unrecognized compensation expense for the restricted stock units as of June 30, 2018 was $38.8 million and is subject to the performance condition explained above.

The Communicated Option Awards are presented as a stock-based compensation liability which was revalued at each reporting period with the change in fair value recorded to compensation expense. As of December 31, 2017 and June 30, 2018, the stock-based compensation liability was $15.4 million and $0, respectively. As of the date of the modification of the Communicated Option Awards, the stock-based compensation liability was $18.2 million.

The fair value of the Communicated Option Awards classified as liabilities was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted in the following table:

	Six months ended June 30,	
	2017	2018
Risk-free interest rate	1.58%	2.49%
Volatility	49.96%	34.13%
Expected dividend yield	0.00%	0.00%
Expected life	3.2	2.9

The weighted-average fair value for Communicated Option Awards granted during the six months ended June 30, 2017 and 2018 was $11.22 and $14.00, respectively. The Company’s shares are not traded in any public market. The common stock value as of the date of grant was based on the share price of

recent equity issuances, if available. If there were no such recent transactions, the Company's share valuation was estimated. As of December 31, 2017, the date at which the stock-based compensation liability was remeasured at fair value, the common stock price was based on the recent equity issuances with third party investors, who were not previous shareholders of the Company. As of the date of the modification of the Communication Option Awards, which resulted in the settlement of the stock-based compensation liability, the common stock price was estimated utilizing a hybrid method, a combination of the Probability Weighted Expected Return Method ("PWERM") and Option Pricing Model ("OPM"). The estimate incorporated a near-term IPO scenario using PWERM weighted at 80%. Other near-term exit events, a long-term stay private case, and dissolution were all considered as non-IPO scenarios using OPM, and were weighted at 20%. The estimate also reflected a 10% and 15% discount for lack of marketability under PWERM and OPM, respectively. The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period.

The fair value of the stock options issued was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted in the following table:

	Six months ended June 30, 2018
Risk-free interest rate	2.84%
Volatility	42.18%
Expected dividend yield	0.00%
Expected life	6

The weighted average fair value for the stock options granted during the six months ended June 30, 2018 was $12.91. The Company's shares are not traded in any public market. For purposes of determining the fair value of the Company's common stock for the grants made in June 2018, the Company utilized a hybrid method, a combination of the PWERM and OPM as described above. The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period.

Note 10—Commitments and Contingencies

Capital stock transactions—The Company has determined that there have been defects with respect to certain capital stock transactions, including stock issuances and a reverse stock split, which were not effected in accordance with the requirements of applicable law. The Company could be subject to claims based on the defects. The Company believes any loss as a result of such defects is remote.

Legal—In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

Lease commitments—The Company has various noncancelable operating leases related to office spaces and manufacturing facilities in Carlsbad, California. In 2017, the Company entered into a new operating lease for office space and manufacturing facilities and abandoned its old leases. The Company recorded an expense and a corresponding liability of $0.2 million as of December 31, 2017 as a result of the lease abandonment, which represents the fair value of the lease termination costs upon initial measurement. The liability includes the estimated costs, net of estimated subleasing proceeds, the Company expects to incur during the lease term using the credit-adjusted risk-free interest rate. The initial expense was recorded in selling, general and administrative expenses in the statement of operations in the fourth quarter of 2017. The initial liability measured at fair value less amortization is included in accrued expenses and other liabilities on the accompanying balance sheet as of December 31, 2017 and June 30, 2018. In periods subsequent to initial measurement, changes to the liability will be measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

Some of these agreements have escalating rent payment provisions. Rent expense under such agreements is recognized on a straight-line basis. Total rent expense for the six months ended June 30, 2017 and 2018 was $0.1 million and $0.2 million, respectively.

Future minimum rental payments due are as follows (in thousands):

Years Ending December 31,	
2018 (remaining six months)	$ 243
2019	500
2020	514
2021	528
2022	432
Thereafter	2,363
Total	$4,580

Note 11—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the dermatology segment and the vascular segment.

In deciding how to allocate resources and assess performance, the Company’s chief operating decision maker regularly evaluates the sales and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to the Company and not specific to a particular segment; therefore, these amounts are not evaluated by the Company’s chief operating decision maker on a segmented basis.

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

The following tables summarize segment performance for the six months ended June 30, 2017 and 2018 (in thousands):

	Six months ended June 30,	
	2017	2018
Vascular	$ 25	$ 184
Dermatology	2,618	2,021
Net revenue	$ 2,643	$ 2,205
Vascular	$ 7	$ 471
Dermatology	1,806	1,255
Cost of revenue	$ 1,813	$ 1,726
Vascular	$ 18	$ (287)
Dermatology	812	766
Gross profit	$ 830	$ 479

Generally, all assets are common assets, except for demonstration lasers and lasers placed with customers, which are a subset of property and equipment. Demonstration lasers and lasers placed with customers aggregated in the vascular segment was $0.2 million and $1.0 million as of December 31, 2017 and June 30, 2018, respectively. Demonstration lasers and lasers placed with customers aggregated in the dermatology segment was $0.3 million and $0.6 million as of December 31, 2017 and June 30, 2018, respectively.

No sales to an individual customer or country other than the United States accounted for more than 10% of net revenue for the six months ended June 30, 2017 or 2018. Net revenue, classified by the major geographic areas in which our customers are located, was as follows:

	Six months ended June 30,	
	2017	2018
United States	$ 2,456	$ 1,936
All other countries	187	269
Net revenue	$ 2,643	$ 2,205

Note 12—Subsequent Events

The Company has evaluated subsequent events through August 24, 2018, the date these financial statements were issued.

Ra Medical Systems, Inc

Notes to Interim Condensed Financial Statements (Unaudited)—(Continued)

Reincorporation in Delaware

On July 14, 2018, the Company reincorporated in Delaware and established the par value of each share of common stock to be $0.0001. In addition, the number of authorized shares of common stock was increased to 25,000,000. In connection with the reincorporation, common stock and additional paid-in capital amounts in these financial statements have been adjusted to reflect the par value of common stock. All share information included in these financial statements has been adjusted to reflect this reincorporation.

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Shares

RA MEDICAL SYSTEMS, INC.

PROSPECTUS

Piper Jaffray **Cantor**

SunTrust Robinson Humphrey

Nomura **Maxim Group LLC**

, 2018

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses to be paid by the Registrant, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the SEC registration fee, the FINRA filing fee, and the exchange listing fee.

	Amount to be Paid
SEC registration fee	$ 10,738.13
FINRA filing fee	$ 13,437.50
The New York Stock Exchange listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ 24,175.63

* To be provided by amendment

Item 14. Indemnification of Directors and Officers.

On completion of this offering, as permitted by Section 102(b)(7) of the Delaware General Corporation Law, the Registrant's amended and restated certificate of incorporation and amended and restated bylaws will contain provisions that eliminate the personal liability of the Registrant's directors and executive officers for monetary damages for breach of their fiduciary duties as directors or officers.

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, executive officer, employee or agent of the corporation or is or was serving at the request of a corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, the amended and restated certificate of incorporation and amended and restated bylaws of the Registrant will provide that:

> The Registrant shall indemnify its directors and officers for serving the Registrant in those capacities or for serving other business enterprises at the Registrant's request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the

best interests of the Registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

The Registrant may, in its discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

The Registrant is required to advance expenses, as incurred, to its directors and officers in connection with defending a proceeding, except that such director or officer shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

The Registrant will not be obligated pursuant to the amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person, except with respect to proceedings authorized by the Registrant's board of directors or brought to enforce a right to indemnification.

The rights conferred in the amended and restated certificate of incorporation and amended and restated bylaws are not exclusive, and the Registrant is authorized to enter into indemnification agreements with its directors, officers, employees, and agents and to obtain insurance to indemnify such persons.

The Registrant may not retroactively amend the bylaw provisions to reduce its indemnification obligations to directors, officers, employees, and agents.

The Registrant has entered into indemnification agreements with its directors and executive officers that provide the maximum indemnity allowed to directors and executive officers by Section 145 of the Delaware General Corporation Law and also to provide for certain additional procedural protections, in addition to the indemnification provided for in its amended and restated certificate of incorporation and bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The Registrant has purchased and currently intends to maintain insurance on behalf of each and any person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The Underwriting Agreement (Exhibit 1.1 hereto) provides for indemnification by the underwriters of the Registrant and its executive officers and directors, and by the Registrant of the underwriters, for certain liabilities, including liabilities arising under the Securities Act.

See also the undertakings set out in response to Item 17 herein.

Item 15. Recent Sales of Unregistered Securities.

Since January 1, 2015, the Registrant has issued and sold the following securities:

Common Stock Issuances

(a) From August 2016 to May 2017 the Registrant sold 667,500 shares of its common stock, at a purchase price of $8.00 per share, to investors in connection with its 2016 financing for aggregate cash consideration of $5.3 million.

(b) On August 30, 2016, the Registrant issued 16,649 shares of its common stock to a service provider as consideration for services rendered.

(c) From September 2017 to May 2018 the Registrant sold 731,280 shares of its common stock, at a purchase price of $25.00 per share, to investors in connection with its 2017 financing for aggregate cash consideration of $18.3 million.

The offers, sales, and issuances of the securities described in Items 15(a), 15(b), and 15(c) were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. With respect to the offers, sales, and issuances of the securities described in Items 15(a) and 15(c), all purchasers were "accredited investors" as that term is defined under Item 501 of Regulation D. In each case, the issuances were made, without any general solicitation or advertising, to a limited number of sophisticated purchasers with knowledge and experience of financial and business matters related to an investment in the Company's securities. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Each of the purchasers of securities had adequate access, through employment, business or other relationships, to information about the Registrant.

Option and Restricted Stock Unit Issuances—Non-Executive Employees

Pursuant to the terms of its 2018 Stock Compensation Plan, the Registrant granted to its non-executive employees, consultants and other service providers (i) options to purchase an aggregate of 680,900 shares of its common stock at exercise prices of $28.94 per share on June 4, 2018; and (ii) 481,906 restricted stock units effective June 8, 2018.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Registrant believes the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The sales of these securities were made without any general solicitation or advertising.

Option and Restricted Stock Unit Issuances—Executive Officers and Directors

Pursuant to the terms of its 2018 Stock Compensation Plan, the Registrant granted to certain of its officers and directors (i) options to purchase an aggregate of 1,221,000 shares of its common stock at exercise prices of $28.94 per share on June 4, 2018; and (ii) 858,926 restricted stock units effective June 8, 2018.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Registrant believes the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder because the issuance of securities to the recipients did not involve a public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof. All recipients had adequate access, through their relationships with the Registrant, to information about the Registrant. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
1.1*	Form of Underwriting Agreement.
3.1#	Certificate of Incorporation of the Registrant, as currently in effect.
3.2	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the completion of this offering.
3.3#	Bylaws of the Registrant, as currently in effect.
3.4	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the completion of this offering.
4.1#	Specimen common stock certificate of the Registrant.
5.1*	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
10.1#	Lease Agreement by and between the Registrant and Lloyd Wells Gift Trust dated November 24, 1987, for the premises located at 2070 Las Palmas Drive, Carlsbad, California 92011 dated as of August 17, 2017.
10.2+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.3+#	Ra Medical Systems, Inc. 2018 Stock Compensation Plan and Forms of Award Agreement thereunder.
10.4+*	Ra Medical Systems, Inc. 2018 Equity Incentive Plan and Forms of Award Agreement thereunder.
10.5+*	Ra Medical Systems, Inc. 2018 Employee Stock Purchase Plan.
10.6+	Ra Medical Systems, Inc. Executive Incentive Compensation Plan.
10.7+#	Ra Medical Systems, Inc. Form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement for executive officers.
10.8+#	Change in Control and Severance Agreement, by and between the Registrant and Dean Irwin, dated as of July 13, 2018.
10.9+#	Change in Control and Severance Agreement, by and between the Registrant and Melissa Burstein, dated as of July 13, 2018.
10.10+#	Change in Control and Severance Agreement, by and between the Registrant and Jeffrey Kraws, dated as of July 13, 2018.
10.11+#	Change in Control and Severance Agreement, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018.
10.12+#	Confirmatory Employment Letter, by and between the Registrant and Dean Irwin, dated as of July 13, 2018.
10.13+#	Confirmatory Employment Letter, by and between the Registrant and Melissa Burstein, dated as of July 13, 2018.
10.14+#	Confirmatory Employment Letter, by and between the Registrant and Jeffrey Kraws, dated as of July 13, 2018.
10.15+#	Confirmatory Employment Letter, by and between the Registrant and Andrew Jackson, dated as of July 13, 2018.

Exhibit Number	Description
21.1#	List of Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP Independent Registered Public Accounting Firm.
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1	Power of Attorney (see pages II-6 and II-7 of the Registration Statement on Form S-1 filed July 16, 2018 and the signature page to this Form S-1).

* To be filed by amendment.
+ Indicates management contract or compensatory plan.
# Previously filed.

(b) Financial Statement Schedules.

All financial statement schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or related notes.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing as specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Carlsbad, State of California, on August 24, 2018.

RA MEDICAL SYSTEMS, INC.

By: /s/ Dean Irwin
Dean Irwin
Chief Executive Officer, Co-President, Chief Technology Officer, Chairman of the Board of Directors
(Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dean Irwin and Andrew Jackson, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities (including his or her capacity as a director and/or officer of Ra Medical Systems, Inc.), to sign any and all amendments (including post-effective amendments or any abbreviated registration statement and any amendments thereto filed) to this Registration Statement, and to sign any and all additional registration statements for the same offering covered by this Registration Statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as they, he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated below:

Signature	Title	Date
/s/ Dean Irwin **Dean Irwin**	Chief Executive Officer, Co-President, Chief Technology Officer, and Chairman of the Board of Directors (Principal Executive Officer)	August 24, 2018
/s/ Andrew Jackson **Andrew Jackson**	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	August 24, 2018
* **Melissa Burstein, M.B.A.**	Executive Vice President and Director	August 24, 2018
* **Martin Burstein, M.B.A.**	Director	August 24, 2018

Signature	Title	Date
* **Richard Heymann**	Director of Corporate Strategy and Business Development, and Director	August 24, 2018
* **Maurice Buchbinder, M.D.**	Director	August 24, 2018
* **Martin Colombatto**	Director	August 24, 2018
* **Richard Mejia, Jr.**	Director	August 24, 2018
/s/ Mark E. Saad **Mark E. Saad**	Director	August 24, 2018
/s/ William R. Enquist, Jr. **William R. Enquist, Jr.**	Director	August 24, 2018

* Pursuant to power of attorney

By: /s/ Dean Irwin
Dean Irwin
Attorney-in-fact

EXHIBIT D

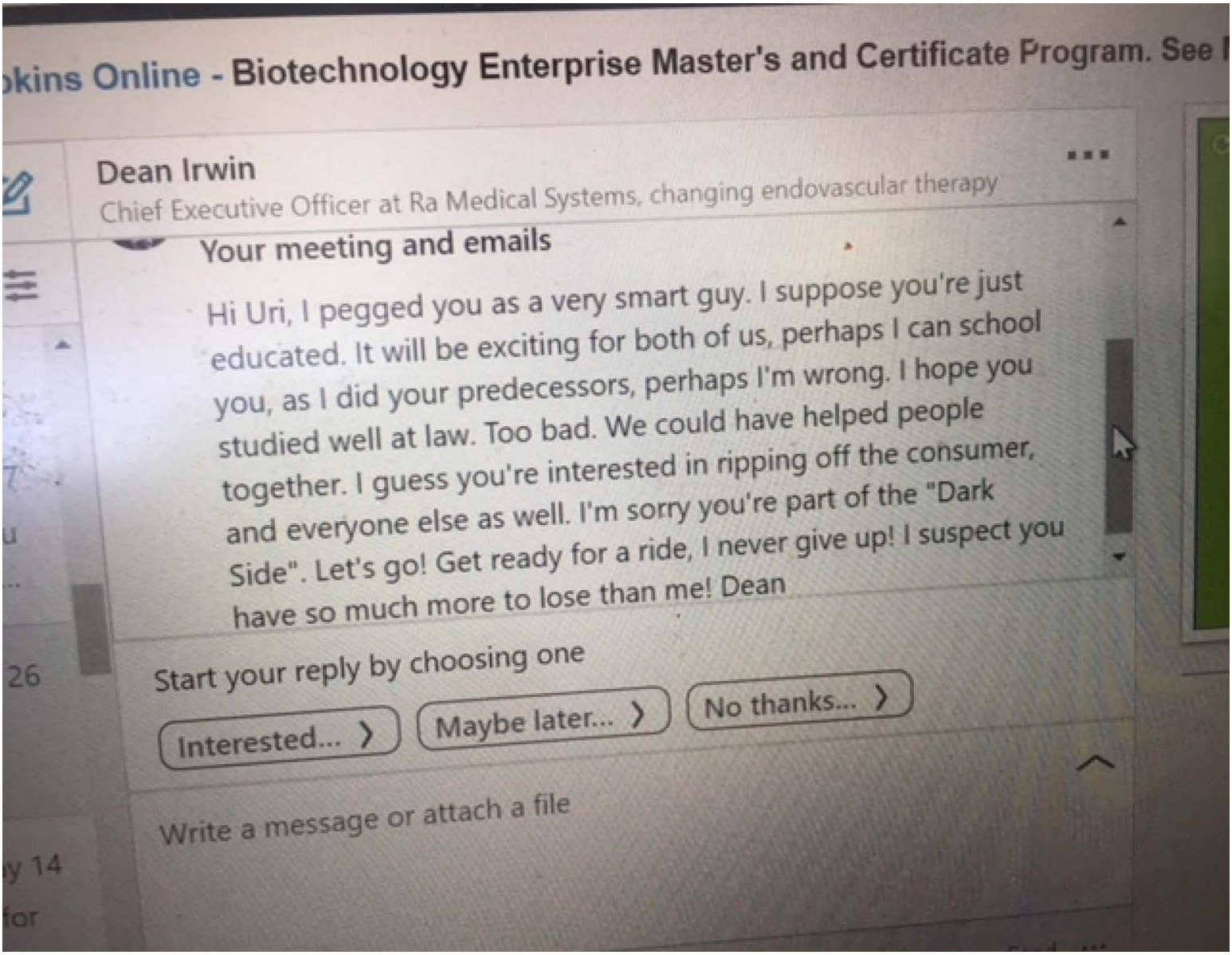

kins Online - Biotechnology Enterprise Master's and Certificate Program. See
Dean Irwin
Chief Executive Officer at Ra Medical Systems, changing endovascular therapy
Your meeting and emails
Hi Uri, I pegged you as a very smart guy. I suppose you're just educated. It will be exciting for both of us, perhaps I can school you, as I did your predecessors, perhaps I'm wrong. I hope you studied well at law. Too bad. We could have helped people together. I guess you're interested in ripping off the consumer, and everyone else as well. I'm sorry you're part of the "Dark Side". Let's go! Get ready for a ride, I never give up! I suspect you have so much more to lose than me! Dean
Start your reply by choosing one
Interested...
Maybe later...
No thanks...
Write a message or attach a file

EXHIBIT E

WINGERT GREBING
WINGERT GREBING BRUBAKER & JUSKIE LLP

One America Plaza | 600 West Broadway
Suite 1200 | San Diego, CA | 92101-3370
Tel (619) 232-8151 | Fax (619) 232-4665

www.wingertlaw.com

Writer's Email:

John R. Wingert, Retired
Roger C. Dyer, Of Counsel

abrubaker@wingertlaw.com

August 22, 2018

VIA FED EX

STRATA Skin Sciences
100 Lakeside Drive, Suite 100
Horsham, Pennsylvania 19044
Attn: Dr. Dolev Rafaeli, Chief Executive Officer

Baker & Hostetler LLP
11601 Wilshire Boulevard, Suite 1400
Los Angeles, California 90025-0509
Attn: Michael R. Matthias, Esq.

STRATA Skin Sciences
2375 Camino Vida Roble, Ste. B
Carlsbad, CA 92011
Attn: Dr. Dolev Rafaeli, Chief Executive Officer

United Corporate Services, Inc.
874 Walker Rd Ste C
Dover, Delaware 19904
Attn: Registered Agent for STRATA Skin Sciences, Inc.

Re: Notice of Contractual Obligation to CEASE AND DESIST Allegations of Patent Infringement and Affirmatively Retract Allegations
Our File No.: RA-0106

Gentlefolks:

Our law firm represents Ra Medical Systems, Inc. This letter serves as Notice to STRATA Skin Sciences that it is under a contractual obligation to **CEASE AND DESIST** accusing Ra Medical of patent infringement and affirmatively retract such allegations.

On May 22, 2018, Uri Geiger, Chairman of the Board of Directors for STRATA Skin Sciences,[1] sent an email to John Hagens of UBS Investment Bank alleging that Ra Medical is engaging in off-label marketing, that Ra Medical is infringing patents licensed to STRATA Skin Sciences by Mount Sinai related to STRATA Skin Sciences' 308 nm Excimer Laser XTRAC product, through Ra Medical's promotion of its Pharos product for the treatment of Vitiligo, and that Ra Medical's Initial Public Offering will result in significant detriment to investors. The email also states these allegations will result in UBS Investment Bank liability and detriment to UBS Investment Bank's brand. When this email was sent by Uri Geiger, UBS Investment Bank

[1] *See* Exhibit A. Uri Geiger was previously a Managing Partner with AccelMed. Uri Geiger sent the May 22, 2018 email from an email address associated with AccelMed the day before he was appointed Chairman of the Board of Directors of STRATA Skin Sciences on May 23, 2018. *See* Exhibit B. AccelMed has approximately 36 percent of the issued and standing voting stock of STRATA. *See* Exhibit C.

had been engaged by Ra Medical in connection with underwriting Ra Medical's Initial Public Offering. Uri Geiger's May 22, 2018 email is enclosed as Exhibit D. Attached to the email were three patents owned by Mount Sinai: U.S. No. 6,979,327, U.S. No. 7,261,729, and U.S. No. 8,387,621, and several images of Ra Medical marketing displays showing Ra Medical's Pharos product.

Specific allegations in the letter include:

> I believe it is my obligation to alert you to some concerning issues regarding the IPO of RA Medical which may result in underwrites liability and effect your brand.
>
> Potential Patent Infringement .... Promoting educating and training the use of the Pharos device for the treatment of Vitiligo is or could be in infringement of the Mount Sinai patents.
>
> To the best of my knowledge, Ra Medical were put on notice of this infringement by Mount Sinai as early as September 2017 through multiple communications, yet the company continues promotion the use of this patented method without seeking license to do so from the patent holder.
>
> To my knowledge, Strata Skin Sciences is the only licensee of this method which is being used with its XTRAC device.
>
> As a side note, with virtually zero relevant 'vascular' revenues, I can't see how this IPO will result in nothing but significant loss to investors.

Exhibit D.

In 2011, Ra Medical and PhotoMedex entered into a Settlement and Release agreement ("Release Agreement") related to several lawsuits brought by Ra Medical and PhotoMedex against one another regarding PhotoMedex's 308 nm Excimer Laser and Ra Medical's Pharos product brought between 2003 and 2009. Under the Release Agreement, the Parties, including their "successors and, all other persons or entities acting by, through, or in concert with them" released each other:

> of and from any and all claims…which do exist *or may in the future exist arising out of or relating to facts events, occurrences, or omissions up to and including the date this Agreement* is fully executed by the parties including, but not limited to, claims brought or which could have been brought in the Litigation or claims which relate to actual or alleged acts of infringement by a Party hereto of any patents, foreign or domestic, which are owned by or licensed to the other Party hereto and which have been issued or are pending as of the Effective Date (collectively, "Claims") § 2, (emphasis added).

Under the Release Agreement, the Parties also agreed that Magistrate Judge (now District Court Judge) Bencivengo of the United States District Court Southern District of California, "shall retain jurisdiction over this Agreement for the purpose of interpreting and enforcing all provisions of this Agreement, and the Parties agree to submit to such jurisdiction upon reasonable notice of any dispute arising." § 18(b). This letter constitutes Ra Medical's reasonable notice[2] to STRATA Skin Sciences, that for at least the reasons below, STRATA Skin Sciences is a successor of PhotoMedex and, accordingly, STRATA Skin Sciences is bound by the Release Agreement and is obligated to CEASE AND DESIST making allegations of patent infringement by Ra Medical and to affirmatively retract these allegations.

In June of 2015, STRATA succeeded to the XTRAC/VTRAC Division and associated assets of PhotoMedex, a Division which, SEC filings by STRATA indicate was a separate and distinct line of business of PhotoMedex, though unincorporated. The doctrine of successor liability applies to a corporation that succeeds to the assets of an unincorporated but clearly separate line of business of another corporation. *Cleveland v. Johnson*, 147 Cal. Rptr. 3d 772, 782 (Cal. Ct. App. 2012).

---

[2] Under § 16 of the Release Agreement, Notices to PhotoMedex are required to be furnished to PhotoMedex, Inc., at 147 Keystone Drive Montgomeryville, PA 18936 Attn: Chief Executive Officer and Corporate Counsel, with a copy to Baker & Hostetler LLP, 12100 Wilshire Boulevard, 15th Floor, Los Angeles, California 90025-71200 Attn: Michael R. Matthias, Esq. (the Baker & Hostetler firm address is now 11601 Wilshire Blvd., Ste. 1400, Los Angeles, California 90025-0509).

PhotoMedex's Pennsylvania address moved to 100 Lakeside Drive, Suite 100 Horsham, Pennsylvania 19044 (*see* Exhibit M) after the Release Agreement was executed. STRATA Skin Sciences now currently resides at that same address: 100 Lakeside Drive, Suite 100 Horsham, Pennsylvania 19044. (*see* Exhibit A). Further, you were the Chief Executive Officer of PhotoMedex from 2006 to 2017 *see* Exhibit B (*see* Exhibit N—the July 4, 2011 Form 8-K Filing by PhotoMedex indicates Dennis McGrath had held the position as well).

Accordingly, pursuant to the Release Agreement, this Notice is addressed to Dr. Dolev Rafaeli at STRATA Skin Sciences both at STRATA Skin Sciences' 100 Lakeside Drive address and its California Principal Place of Business address (*see* Exhibit O); to Mr. Matthias at Baker & Hostetler; and to the Registered Corporate Agent for STRATA Skin Sciences, United Corporate Services, Inc.

Specifically, on June 23, 2015, PhotoMedex announced the sale of its XTRAC and VTRAC treatment business to Mela Sciences (the former name of STRATA Sciences, *see* Exhibit E). *See* Exhibit F. The XTRAC/VTRAC division of PhotoMedex was "part of two reportable segments within PhotoMedex, Inc." Exhibit G, page F-8. "The Division [was] comprised of certain standalone legal entities for which discrete financial information was available." *Id.* The purchase price was $4.25 million. *Id.* at Ex. 10.4 Section 2.2. In relation, on June 22, 2015, PhotoMedex filed an assignment with the USPTO evidencing the assignment of several patents to Mela Sciences, including for example U.S. No. 7,886,749 "Treatment of Skin Disorders with UV Light and Cooling" and U.S. No. 7,276,059 "Treatment of Skin Disorders with UV Light and Cooling," that list Dean Irwin as inventor. *See* Exhibit H.

Further, the three Mount Sinai patents STRATA Skin Sciences now alleges to license exclusively[3] are the same patents previously licensed to PhotoMedex in connection with its XTRAC business. In 2006, PhotoMedex entered into a License Agreement with Mount Sinai to license U.S. Patent No. 6,979,327 and U.S. Application Serial No. 11/174,437 [now U.S. No. 7,261,729], "and any divisionals, continuations, continuations-in-part, extensions, supplemental protection certificates, substitutions, re-examinations, renewals, reissues, and any and all claims under patents and patent applications corresponding thereto including without limitation all foreign patent filings and Letters Patent issued thereon". *See* Exhibit 10.1 of Exhibit J, at § 1(f), and § 2(a). This would include now-issued U.S. No. 8,387,621, which is a continuation of U.S. No. 7,261,729.

PhotoMedex had entered into this patent license to combine the licensed technology with its XTRAC laser system. *Id.* at Ex. 99.1 of Exhibit J. In connection with its 2015 succession to the PhotoMedex XTRAC/VTRAC Division, STRATA Skin Sciences was presumably assigned PhotoMedex's exclusive license to the Mount Sinai patents to STRATA Skin Sciences in or around 2015 under Section 14 of the license agreement between PhotoMedex and Mount Siniai:

> [PhotoMedex] may assign this Agreement to a successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, with prompt written notice to [Mount Sinai] of any such assignment. This Agreement shall inure to the benefit of and be binding upon the parties and their respective lawful successors and assigns.

See Exhibit 10.1 of Exhibit J, § 14.

[3] *See* Exhibit D (Uri email). On August 3, 2015, STRATA, under its former name Mela Sciences, made an 8-K filing with the SEC stating "we secured a license from the Mount Sinai School of Medicine, New York, New York, which granted us exclusive rights to a patent directed to the use of excimer lasers in the treatment of vitiligo." *See* Exhibit I.

Several other facts demonstrate STRATA Skin Sciences is a successor of PhotoMedex. As noted *supra*, the same individual who served as the Chief Executive Officer of PhotoMedex is now the Chief Executive Officer of STRATA Skin Sciences. Likewise, previous Chairman of the Board of Directors of STRATA Skin Sciences, Jeffrey O'Donnell, served as the President and Chief Executive Officer of PhotoMedex, Inc. from 1999 to 2009. *See* Exhibit K. As another example, Samuel Navarro, who used to serve on the Board of Directors of PhotoMedex, has served on the Board of Directors of STRATA Skin Sciences since 2014. *See* Exhibits A, L. Also noted *supra* in n. 2, STRATA Skin Sciences' 100 Lakeside Drive, Suite 100 Horsham, Pennsylvania 19044 is the same address PhotoMedex held after the Release Agreement was executed. *See* Exhibit M. As another example, in the August 13, 2018 Q2 2018 Results Earnings Conference Call of STRATA Skin Sciences, Dr. Rafaeli stated:

> We see a lot of progress on the sales side. We see a lot of progress with the accounts. Stopping this deterioration in installed base that has lasted six quarters and doing this basically on a dime. I mean, stepping in and communicating the right messages and telling them that we're back here, we're here to provide value to them, we're here to make money ourselves, we are here to bring this business *back at least to where it was in 2015 and if not more, and we're here to do this fast. Last time, when we did this, it took us two and half years. If you want to relate where we are today in comparison to the 2011 to 2015, timeline,* then from a perspective of getting the DTC up and running and getting the patients appointments up and running, we are now in the beginning of 2014. *From the perspective of getting the clinics to perform and the utilization of the devices, we are in the early 2013 numbers. We did not provide these numbers here but they're all publicly available as part of the PhotoMedex previous disclosures where in the beginning of 2013, it is moving fast, it is moving faster than what I anticipated.*

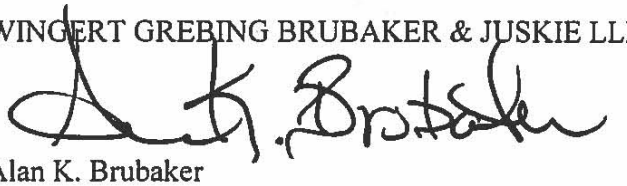
Exhibit P (emphasis added). *See McClellan v. Northridge Park Townhome Owners Ass'n, Inc.*, 89 Cal. App. 4th 746, 756 (Cal. Ct. App. 2001) (noting as a general matter that corporations cannot escape liability by a change of name or shift in assets when and where it is shown that the new corporation is a continuation of the old one). For at least these reasons, STRATA Skin Sciences constitutes a successor of PhotoMedex under the Release Agreement and is thereby bound by the mutual release under that Agreement.

Accordingly, Ra Medical demands that STRATA Skin Sciences CEASE AND DESIST alleging patent infringement by Ra Medical , and that STRATA Skin Sciences affirmatively retracts its allegations of patent infringement including the allegations and statements made to UBS in Uri Geiger's May 22, 2018 letter. Unless Ra Medical receives confirmation in writing that STRATA Skin Sciences has complied with this demand, accompanied by copies of the

correspondence sent by STRATA Skin Sciences retracting its allegations by on or before close of business PDT September 4, 2018, Ra Medical will be contacting Judge Bencivengo, District Judge for the United States District Court for the Southern District of California to enforce the Release Agreement.

Very truly yours,

WINGERT GREBING BRUBAKER & JUSKIE LLP



Alan K. Brubaker

AKB:tn
Enclosures
cc: Ra Medical Systems, Inc.
Schmeiser Olsen Watts LLP