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Registration No. 333-226296

PROSPECTUS

STRATA Skin Sciences, Inc.

15,893,745 Shares of Common Stock

This prospectus relates to the resale of up to an aggregate of 15,893,745 shares of our common stock, par value $0.001 per share (the "Common Stock"), of which (i) 12,112,627 shares of Common Stock were issued to Accelmed Growth Partners L.P. ("Accelmed") by STRATA Skin Sciences, Inc. (the "Company") pursuant to a securities purchase agreement dated March 30, 2018 by and between Accelmed and the Company (the "Accelmed SPA"); (ii) 967,685 shares of Common Stock were issued to Broadfin Healthcare Master Fund, Ltd. ("Broadfin") pursuant to a securities purchase agreement dated March 30, 2018 by and between Broadfin and the Company (the "Broadfin SPA"); (iii) an aggregate of 949,953 shares of Common Stock were issued to Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (together with Sabby Healthcare Master Fund, Ltd., "Sabby") pursuant to a securities purchase agreement dated March 30, 2018 by and between Sabby and the Company (the "Sabby SPA"); (iv) 931,740 shares of Common Stock were issued to Gohan Investments, Ltd. ("Gohan") pursuant to a subscription agreement by and between Gohan and the Company (the "Gohan Subscription Agreement") and (v) 931,740 shares of Common Stock were issued to Dr. Dolev Rafaeli (together with Accelmed, Broadfin, Sabby and Gohan, the "Purchasers") pursuant to a subscription agreement by and between Dr. Dolev Rafaeli and the Company (the "Dolev Subscription Agreement", together with the Accelmed SPA, Broadfin SPA, Sabby SPA and Gohan Subscription Agreement, the "Agreements").

The shares of Common Stock will be resold from time to time by the entities and persons listed in the section titled "Selling Securityholders" on page 22, which we refer to as the selling securityholders. We are not selling any securities under this prospectus and we will not receive any of the proceeds from the sale of shares of our Common Stock by the selling securityholders. The selling securityholders will receive all of the proceeds from any sales of the shares of our Common Stock offered hereby. However, we will incur expenses in connection with the registration of the shares of our Common Stock offered hereby, including legal and accounting fees.

The selling securityholders may sell the shares of Common Stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how a selling securityholder may sell its shares of Common Stock in the section titled "Plan of Distribution" on page 24.

Our Common Stock is quoted on The Nasdaq Capital Market, or Nasdaq, under the symbol "SSKN." On September 14, 2018, the last reported sale price of our Common Stock was $3.49 per share.

Investing in our securities involves risks. See "Risk Factors" beginning on page 4 of this prospectus.

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

THE DATE OF THIS PROSPECTUS IS SEPTEMBER 24, 2018.

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INFORMATION CONTAINED IN THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference into this prospectus. We have not, and the selling securityholders have not, authorized anyone to provide you with additional or different information. These securities are not being offered in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the documents incorporated by reference, regardless of the time of delivery of this prospectus or of any sale of our Common Stock. Unless the context otherwise requires, references to "we," "our," "us," or the "Company" in this prospectus mean STRATA Skin Sciences, Inc., together with its subsidiaries.

PROSPECTUS SUMMARY

The following is only a summary. We urge you to read the entire prospectus, including the more detailed consolidated financial statements, notes to the consolidated financial statements and other information included herein or incorporated by reference from our other filings with the U.S. Securities and Exchange Commission, or SEC. Investing in our securities involves risks. Therefore, please carefully consider the information provided under the heading "Risk Factors" starting on page 4.

Overview

The Company is a medical technology company focused on the therapeutic and aesthetic dermatology market. The Company's sales include the following products: XTRAC® laser and VTRAC® excimer lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions; and the STRATAPEN® MicroSystems, a micropigmentation device.

The XTRAC device is utilized to treat psoriasis, vitiligo and other skin diseases. The XTRAC device received clearance from the U.S. Food and Drug Administration (the "FDA") in 2000 and has since become a widely recognized treatment among dermatologists. The system delivers targeted 308nm ultraviolet light to affected areas of skin, leading to psoriasis clearing and vitiligo repigmentation, following a series of treatments. As of June 30, 2018, there were 746 XTRAC systems placed in dermatologists' offices in the United States under the Company's recurring revenue model. Under the recurring revenue model, the XTRAC system is placed in a physician's office and fees are charged on a per procedure basis or a fee is charged on a periodic basis not to exceed an agreed upon number of procedures. The XTRAC system's use for psoriasis is covered by nearly all major insurance companies, including Medicare. The VTRAC Excimer Lamp system, offered internationally in addition to the XTRAC system, provides targeted therapeutic efficacy demonstrated by excimer technology with the simplicity of design and reliability of a lamp system. There are approximately 7.5 million people in the United States and up to 125 million people worldwide suffering from psoriasis, and 1% to 2% of the world's population suffers from vitiligo. In 2017, over 335,000 XTRAC laser treatments were performed on approximately 21,000 patients in the United States.

During 2017, the Company entered into an agreement to license the exclusive US distribution rights for the Ellipse family of products, Nordlys, from Ellipse A/S, the Danish manufacturer, through August 9, 2020. The license fee amounted to approximately $355,000 over the initial term of the agreement with a present value as of the effective date of the agreement of $286,000. Effective March 31, 2018, as result of the change in management (See Recent Developments), the Company had determined that it will no longer continue to market the Nordlys and the distribution rights agreement was terminated effective May 31, 2018.

Recent Developments

Equity Financing Agreements

On March 30, 2018, the Company entered into the Agreements pursuant to which the Company issued 15,893,745 (including 153,004 shares issued pursuant to the Retained Risk (defined below) provision of the Agreements) shares of Common Stock to a group of investors led by Accelmed for gross proceeds of approximately $17.0 million at a per share price of $1.08. The following descriptions of the Agreements and the Leak-Out Agreements (as defined below) are not complete and are subject to and qualified in their entirety by reference to the Agreements and the Leak-Out Agreements, respectively, copies of which are filed as exhibits hereto and are incorporated herein by reference.

Accelmed Stock Purchase Agreement

The Company issued 12,112,627 shares (including 75,590 shares of Common Stock issued pursuant to the Retained Risk provision of the Accelmed SPA) of Common Stock to Accelmed for gross proceeds of approximately $13.0 million, pursuant to the Accelmed SPA. Pursuant to the Accelmed SPA, the Company reimbursed Accelmed

for its legal, consulting, due diligence and certain costs related to the transaction, including the reasonable legal fees, disbursements and related charges of $500,000 at closing. The Accelmed SPA also requires that the Company indemnify Accelmed for certain items identified in Accelmed SPA. Pursuant to the Accelmed SPA, if the Company incurs losses related to certain tax obligations, legal fees, insurance premiums or fees to any placement agents, financial or investment advisors or brokers in connection with transactions contemplated by the Accelmed SPA (each a "Retained Risk"), then the Company is required to issue additional shares of Common Stock as compensation for such loses to Accelmed.

Broadfin and Sabby Stock Purchase Agreements

In connection with the Accelmed investment, the Company entered into the Broadfin SPA and Sabby SPA on March 30, 2018, each for $1.0 million with two sets of current stockholders, Broadfin and Sabby. Upon closing of these transactions, Broadfin and Sabby received 967,685 shares and 949,953 shares, respectively (including a combined total of 65,786 shares of Common Stock issued under the Retained Risk provisions of the Broadfin SPA and Sabby SPA) of the Company's Common Stock at a price per share of $1.08.

In further consideration of entering into the Sabby SPA and Broadfin SPA, Sabby and Broadfin, each entered into separate agreements restricting their abilities to sell their holdings (each, a "Leak-Out Agreement" and together, the "Leak-Out Agreements"). Under the terms of each of the respective Leak-Out Agreements, the stockholder has agreed that until May 29, 2021, the stockholder shall not sell, dispose or otherwise transfer, directly or indirectly, (including, without limitation, any sales, short sales, swaps or any derivative transactions that would be equivalent to any sales or short positions) any shares of Common Stock of the Company held by the stockholder or issuable to the stockholder upon conversion of shares of the Company's Series C Preferred Stock, $0.10 per share (the "Preferred Stock") held by the stockholder, (a) if prior to April 1, 2019, at a price per share less than $1.296, subject to adjustment for reverse and forward stock splits and the like, or (b) thereafter, at a price per share reflecting less than the price set forth on the schedule in the Leak-Out Agreements, subject to adjustment for reverse and forward stock splits and the like, unless, (1) in the case of either clauses (a) or (b), otherwise approved by the Company's Board of Directors, (2) in the case of either clause (b), under a shelf prospectus or such other controlled offering as may be agreed to by the Principal Stockholders (as defined in the Sabby SPA and Broadfin SPA, as applicable) or (3) in the case of either clauses (a) or (b), in a sale pursuant to which any other stockholder(s) of the Company are offered the same terms of sale, including in a merger, consolidation, transfer or conversion involving the Company or any of its subsidiaries.

Pursuant to the Broadfin SPA and Sabby SPA, if the Company incurs losses related to a Retained Risk, the Company is required to issue additional shares of Common Stock as compensation for such loses to Broadfin and Sabby, respectively.

Subscription Agreements

The Company also entered into two separate subscription agreements in connection with the Accelmed investment: (i) a subscription agreement with Gohan Investments, Ltd. for $1.0 million to purchase 931,740 shares (including 5,814 shares of Common Stock issued under the Retained Risk provisions) of Common Stock at $1.08 per share; and (ii) a subscription agreement with Dr. Dolev Rafaeli for $1.0 million to purchase 931,740 (including 5,814 shares issued under the Retained Risk provisions) shares of Common Stock at $1.08 per share upon closing under the Accelmed SPA.

Pursuant to the subscription agreements, if the Company incurs losses related to a Retained Risk, the Company is required to issue additional shares of Common Stock as compensation for such loses to Gohan Investments, Ltd. and Dr. Dolev Rafaeli.

Change of Control

The closing of the transactions contemplated by Agreements (the "Transactions") and the issuance of shares of Common Stock to the purchasers resulted in a change of control of the Company and a change in management and composition of the Company's Board of Directors. Following the Transactions, Accelmed controls a majority of the outstanding shares of the Company's Common Stock. As of September 10, 2018, Accelmed holds (a) approximately 40% of the issued and outstanding voting stock of the Company and (b) approximately 36% of the Company's issued and outstanding capital stock, assuming the conversion of all outstanding shares of the Company's Series C Preferred Stock (but excluding the exercise of outstanding stock options and warrants).

Company Information

We were incorporated in the State of Delaware under the name Electro-Optical Sciences, Inc. on September 3, 1997. Our principal executive offices are located at 100 Lakeside Drive, Suite 100, Horsham, Pennsylvania 19044. Our telephone number is (215) 619-3200 and our website address is *www.strataskinsciences.com*. References in this prospectus to our website address does not constitute incorporation by reference of the information contained on the website.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully review and consider the following risk and all other information, documents or reports included or incorporated by reference in this prospectus and if applicable, any prospectus supplement or other offering materials, including the risks and uncertainties discussed under "Risk Factors" in our most recent Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC"), which is incorporated by reference, in this prospectus, and any updates to those risk factors included from time to time in our periodic and current reports filed with the SEC and incorporated by reference in this prospectus, before making any decision to invest in shares of our Common Stock. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. If any of the events discussed in these risk factors occurs, our business, prospects, results of operations, financial condition and cash flows could be materially harmed. If that were to happen, the trading price of our Common Stock could decline, and you could lose all or part of your investment.

Risks Related to our Financial Condition and Capital Requirements

We have incurred losses for a number of years, and anticipate that we will incur continued losses for the foreseeable future.

Since 1999, we have primarily financed our operations through the sale of our equity securities and have devoted substantially all of our resources to research, development and commercialization of MelaFind, which we discontinued during the year ended December 31, 2017. Our net loss for the year ended December 31, 2017 was approximately $18.8 million, and as of December 31, 2017, we had an accumulated deficit of approximately $229.4 million. Our profitability has been negatively impacted by interest expense related to the June 2015 financing as well as the $11.8 million loss on the extinguishment of debentures in 2017. Our losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity. Since the closing of our acquisition of the XTRAC and VTRAC products in June 2015, we began to recognize revenues of those products, which, together with the proceeds of our financing in May 2018, we expect will provide sufficient cash flow to fund our current operations for the foreseeable future.

Risks Related to our Business Operations

Our laser treatments of psoriasis, vitiligo, atopic dermatitis and leukoderma and any of our future products or services may fail to gain market acceptance, which could adversely affect our competitive position.

We have generated limited worldwide commercial distribution for our products. In the United States, our XTRAC systems are installed at physician offices at no upfront charge to the physician and we are paid on a per-usage method where we retain ownership of the system. We cannot assure you that our products and services will find acceptance in the marketplace to permit us to generate a substantial increase in our revenues.

We also face a risk that other companies in the market for dermatological products and services may be able to provide dermatologists a higher overall return on investment and therefore compromise our ability to increase our base of users and ensure they engage in optimal usage of our products. If, for example, such other companies have products (such as Botox or topical creams for disease management) that require less time commitment from the dermatologist and yield an attractive return on a dermatologist's time and investment, we may find that our efforts to increase our base of users are hindered.

Current Procedural Terminology ("CPT") codes for all procedures are subject to continued reevaluation. Should the Center for Medicaid Services reduce reimbursement for the CPT codes for XTRAC treatment we may see a decline in our recurring revenue business as well as a decline in new XTRAC installations.

Whether a treatment may be delegated and, if so, to whom and to what extent, are matters that may vary state by state, as these matters are within the province of the state medical boards. In states that may be more restrictive in such delegation, a physician may decline to adopt the XTRAC system into his or her practice, because there are too many constraints and complexities and finding other outlets for the physician's time and staff time to be more remunerative. There can be no assurance that we will be successful in persuading such medical boards that a liberal

standard for delegation is appropriate for the XTRAC system, based on its design for ease and safety of use. If we are not successful, we may find that even if a geographic region has wide insurance reimbursement, the region's physicians may decline to adopt the XTRAC system into their practices.

We therefore cannot assure you that the marketplace will be receptive to our excimer laser technology over competing products, services and therapies or that a cure will not be found for the underlying diseases we are focused on treating that makes our product obsolete. Failure of our products to achieve market acceptance could have a material adverse effect on our business, financial condition and results of operations.

The success of our products depends on third-party reimbursement of patients' costs, which could result in potentially reduced prices or reduced demand and adversely affect our revenues and business operations.

Our ability to market our products successfully, especially XTRAC treatments, depends in large part on the extent to which various third parties are willing to reimburse patients or providers for the costs of medical procedures utilizing such products. These third parties include government authorities, private health insurers and other organizations, such as health maintenance organizations, whose patterns of reimbursement may change as a result of new standards for reimbursement determined by these third parties or because of the programs and policies enacted under the Patient Protection and Affordable Care Act of 2010 ("ACA"). For the most part, aesthetic and cosmetic treatments for many usages of STRATAPEN are not covered by insurance and patients pay out of pocket for these treatments.

Third-party payors are systematically challenging the prices charged for medical products and services. They may deny reimbursement if they determine that a prescribed device is not used in accordance with cost-effective treatment methods as determined by the payor, or is experimental, unnecessary or inappropriate. Further, although third parties may approve reimbursement, such approvals may be under terms and conditions that discourage use of the XTRAC system. Accordingly, if less costly drugs or other treatments are available, third-party payors may not authorize or may limit reimbursement for the use of our products, even if our products are safer or more effective than the alternatives.

In addition, medical insurance policies and treatment coverage have been and may be affected by the parameters of the ACA or successor policies enacted by the new administration. While the ACA's stated purpose is to expand access to coverage, it also mandates certain requirements regarding the types and limitations of insurance coverage. There can be no guarantee that the changes in coverage under the ACA will not affect the type and level of reimbursement for our products.

Although we have received reimbursement approvals from a majority of private healthcare plans for the XTRAC system, we cannot give assurance that these private plans will continue to adopt or maintain favorable reimbursement policies or accept the XTRAC system in its clinical role as a second-line therapy in the treatment of psoriasis. Additionally, third-party payors may require further clinical studies or changes to our pricing structure and revenue model before authorizing or continuing reimbursement.

As of March 22, 2018, we estimate, based on published coverage policies and on payment practices of private and Medicare insurance plans, that more than 90% of the insured population in the U.S. is covered by insurance coverage or payment policies that reimburse physicians for using the XTRAC system for treatment of psoriasis. We can give no assurance that health insurers will not adversely modify their reimbursement policies for the use of the XTRAC system in the future.

Any failure in our customer education efforts could significantly reduce product marketing.

It is important to the success of our marketing efforts to educate physicians and technicians how to properly use our products. We rely on physicians to spend their time and money to participate in our pre-installation educational sessions. Moreover, if physicians and technicians use our products improperly, they may have unsatisfactory patient outcomes or, in the case of the XTRAC system, cause patient injury, which may give rise to negative publicity or lawsuits against us, any of which could have a material adverse effect on our reputation, revenues and results of operations.

If revenue from a significant customer declines, we may have difficulty replacing the lost revenue, which would negatively affect our results and operations.

In our international business, we depend for a material portion of our sales in the international arena on several key sub-distributors, and especially on The Lotus Global Group, Inc., doing business as GlobalMed Technologies Co., or GlobalMed, which is our master distributor over the XTRAC and VTRAC products. If we lose GlobalMed or one of these sub-distributors, our sales of phototherapy products are likely to suffer in the short term, which could have a negative effect on our revenues and results of operations.

If we fail to manage our sales and marketing force or to market and distribute our products effectively, we may experience diminished revenues and profits.

There are significant risks involved in building and managing our sales and marketing force and marketing our products, including our ability:

- to hire, as needed, a sufficient number of qualified sales and marketing personnel with the aptitude, skills and understanding to market our products;
- to adequately train our sales and marketing force in the use and benefits of all our products and services, thereby making them more effective promoters;
- to manage our sales and marketing force and our ancillary channels (e.g., telesales) such that variable and semi-fixed expenses grow at a lesser rate than our revenues; and
- to set the prices and other terms and conditions for treatments using the XTRAC system in a complex legal environment so that they will be accepted as attractive skin health and appropriate alternatives to conventional modalities and treatments.

To increase acceptance and utilization of our products, we may have to expand our sales and marketing programs in the U.S. While we may be able to draw on currently available personnel within our organization to meet this need, we also expect that we will have to increase the number of representatives devoted to the sales and marketing programs and to broaden, through such representatives, the talents we have at our disposal. In some cases, we may look outside our organization for assistance in marketing our products.

We are not the manufacturer of some of our products and sell those products through contractual agreements.

Our STRATAPEN line of products are purchased by us and resold to end users under a distribution agreement. In order to retain this line, we need to achieve certain minimum sales. We cannot assure you that we will continue to achieve a level of sales required to maintain the rights to sell this product.

We are reliant on a limited number of suppliers for production of our products.

Production of our products requires specific component parts obtained from our suppliers. While we believe that we could find alternate suppliers, in the event that our current suppliers fail to meet our needs, a change in suppliers or any significant delay in our ability to have access to such resources could have a material adverse effect on our delivery schedules, business, operating results and financial condition. Moreover, in the event we can no longer utilize this supplier or acquire this resource and must identify a new supplier or substitute a different resource, such change may trigger an obligation for us to comply with additional FDA regulatory requirements including, but not limited to, pre-marketing authorization and Quality System Requirements ("QSR").

Our failure to respond to rapid changes in technology and our applications in the medical devices industry or the development of a cure for skin conditions treated by our products could make our treatment system obsolete.

The medical device industry is subject to rapid and substantial technological development and product innovations. To be successful, we must respond to new developments in technology, new applications of existing technology and new treatment methods. Our financial condition and operating results could be adversely affected if we fail to be responsive on a timely and effective basis to competitors' new devices, applications, treatments or price strategies. For example, the development of a cure for psoriasis, vitiligo, atopic dermatitis or leukoderma would eliminate the need for our XTRAC system for these diseases and would require us to focus on other uses of our technology, which could have a material adverse effect on our business and prospects.

As we develop new products or improve our existing products, we may accelerate the economic obsolescence of the existing, unimproved products and their components. The obsolete products and related components may have little to no resale value, leading to an increase in the reserves we have against our inventory. Likewise, there is a risk that the new products or improved existing products may not achieve market acceptance and therefore may also lead to an increase in the reserves against our inventory.

On March 13, 2017 we notified the FDA that, as of September 30, 2017, we will no longer service the MelaFind device. As the device is subject to both FDA requirements and requirements of certain foreign countries in which the device is still in use, we cannot assure you that a government agency may not make a demand that we either continue to provide support or recall devices still in use and thereby increase our costs and expenses.

We may become subject to product liability lawsuits whether due to misuse of our products by customers or physicians, or otherwise, and other damages imposed on us may exceed our insurance coverage, or we may be subject to claims that are not covered by insurance.

We may be subject to product liability claims from time to time. Our products are highly complex and some are used to treat delicate skin conditions on and near a patient's face. In addition, the clinical testing, manufacturing, marketing and use of certain of our products and procedures may also expose us to product liability, FDA regulatory and/or legal actions, or other claims. If a physician elects to apply an off-label use and the use leads to injury, we may be involved in costly litigation. In addition, the fact that we train technicians whom we do not supervise in the use of our XTRAC system during patient treatment may expose us to third-party claims if those doing the training are accused of providing inadequate training. We presently maintain liability insurance with coverage limits of at least $5,000,000 per occurrence and $5,000,000 in the aggregate, but product liability insurance is expensive and we might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition. In addition, continuing insurance coverage may also not be available at an acceptable cost, if at all. Therefore, we may not be able to obtain insurance coverage that will be adequate to satisfy a liability that may arise. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to its reputation, withdrawal of clinical trial volunteers and loss of revenues. As a result, regardless of whether we are insured, a product liability claim or product recall may result in losses that could result in the FDA taking legal or regulatory enforcement action against us and or our products including recall, and could have a material adverse effect upon our business, financial condition and results of operations.

We must comply with complex statutes prohibiting fraud and abuse, and both we and physicians utilizing our products could be subject to significant penalties for noncompliance.

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include:

- the anti-kickback statute which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs, as modified by the ACA;
- the physician self-referral prohibition, commonly referred to as the Stark Law;
- the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs and;
- the Civil Monetary Penalties Law, which authorizes U.S. Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts. Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both.

As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use of our products by physicians may dissuade physicians from either purchasing or using our products and could have a material adverse effect on our revenues.

If the effectiveness and safety of our devices are not supported by long-term data, and the level of acceptance of our products by dermatologists does not increase or is not maintained, our revenues could decline.

Our products may not be accepted in the market if we do not produce clinical data supported by the independent efforts of clinicians. We received clearance from the FDA for the use of the XTRAC system to treat psoriasis based upon our study of a limited number of patients. Safety and efficacy data presented to the FDA for the XTRAC system was based on studies on these patients. For the treatment of vitiligo, atopic dermatitis and leukoderma, we have received clearance from the FDA for the use of the XTRAC system based primarily on a showing of substantial equivalence to other previously cleared predicate devices. However, we may discover that physicians will expect clinical data on such treatments with the XTRAC system. We also may find that data from longer-term psoriasis patient follow-up studies may be inconsistent with those indicated by our relatively short-term data. If longer-term patient studies or clinical experience indicate that treatment with the XTRAC system does not provide patients with sustained benefits or that treatment with our product is less effective or less safe than our current data suggests, our revenues could decline. In addition, the FDA could then bring legal or regulatory enforcement actions against us and/or our products including, but not limited to, recalls or requirements for pre-market 510(k) authorizations. We can give no assurance that our data will be substantiated in studies involving more patients. In such a case, we may never achieve significant revenues or profitability.

Our failure to obtain or maintain necessary FDA clearances or approvals, or equivalents thereof in the U.S. and relevant foreign markets, could hurt our ability to distribute and market our products.

In both our U.S. and foreign markets, we are affected by extensive laws, governmental regulations, administrative determinations, court decisions and similar constraints. Such laws, regulations and other constraints may exist at the federal, state or local levels in the U.S. and at analogous levels of government in foreign jurisdictions. In addition, the formulation, manufacturing, packaging, labeling, distribution, importation, sale and storage of our products are subject to extensive regulation by various federal agencies, including, but not limited to, the FDA and the FTC, State Attorneys General in the U.S., as well as by various other federal, state, local and international regulatory authorities in the countries in which its products are manufactured, distributed or sold. If we or our manufacturers fail to comply with those regulations, we could become subject to significant penalties or claims, which could harm our results of operations or our ability to conduct our business. In addition, the adoption of new regulations or changes in the interpretations of existing regulations may result in significant compliance costs or discontinuation of product sales and may impair the marketing of our products, resulting in significant loss of net sales. Our failure to comply with federal or state regulations, or with regulations in foreign markets that cover our product claims and advertising, including direct claims and advertising by us, may result in enforcement actions and imposition of penalties or otherwise harm the distribution and sale of its products. Further, our businesses are subject to laws governing our accounting, tax and import and export activities. Failure to comply with these requirements could result in legal and/or financial consequences that might adversely affect our sales and profitability. Each medical device that we wish to market in the U.S. must first receive either 510(k) clearance or Premarket Approval ("PMA") from the FDA unless an exemption applies. Either process can be lengthy and expensive. The FDA's 510(k) clearance process may take from three to twelve months, or longer, and may or may not require human clinical data. The PMA process is much more costly and lengthy. It may take from eleven months to three years, or even longer, and will likely require significant supporting human clinical data. Delays in obtaining regulatory clearance or approval could adversely affect our revenues and profitability. Although we have obtained a PMA for the MelaFind system to aid in the diagnosis of melanoma and 510(k) clearances for our XTRAC system for use in treating psoriasis, vitiligo, atopic dermatitis and leukoderma, these approvals and clearances may be subject to revocation if post-marketing data demonstrates safety issues or lack of effectiveness. Similar clearance processes may apply in foreign countries. Further, more stringent regulatory requirements or safety and quality standards may be issued in the future with an adverse effect on our business. We have ceased manufacturing and marketing MelaFind but must still maintain records for FDA and foreign regulatory purposes.

If required, clinical trials necessary to support a 510(k) notice or PMA application will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

We have filed a 510(k) application for our Multi-Micro Dose™ tip accessory for our XTRAC excimer laser.

For this product and if we acquire or develop a product that requires us to initiate and complete clinical trials necessary to support a 510(k) notice or a PMA application, this process will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in early or later clinical trials.

Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by patients enrolled as subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy may be required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis for any clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. The FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

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 good manufacturing practices under the quality system regulations; filing reports with the FDA 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" 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, some Class III devices are subject to PMA. In general, obtaining PMA to achieve marketing authorization from the FDA is a more onerous process than seeking 510(k) clearance.

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 including standards for device recalls and product labeling. Such reviews and investigations may result in 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.

We must also have the appropriate FDA clearances and/or approvals from other governmental entities in order to lawfully market devices and or/drugs. The FDA, federal, state or foreign governments and agencies may disagree that we have such clearance and/or approvals for all of our products and may take action to prevent the marketing and sale of such devices until such disagreements have been resolved.

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 requires us to disclose payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals at the U.S. federal level made. 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.

Healthcare policy changes may have a material adverse effect on us.

Healthcare costs have risen significantly over the past decade. As a result, there have been and continue to be proposals by federal, state and foreign governments and regulators as well as third-party insurance providers to limit the growth of these costs. Among these proposals are regulations that could impose limitations on the prices we will be able to charge for our products, the amounts of reimbursement available for our products from governmental agencies or third-party payors, requirements regarding the usage of comparative studies, technology assessments and healthcare delivery structure reforms to determine the effectiveness and select the products and therapies used for treatment of patients. While we believe our products provide favorable clinical outcomes, value and cost efficiency, the resources necessary to demonstrate this value to our customers, patients, payors, and regulators is significant and may require longer periods of time and effort in which to obtain acceptance of our products. There is no assurance that our efforts will be successful, and these limitations could have a material adverse effect on our financial position and results of operations.

These changes and additional proposed changes in the future could adversely affect the demand for our products as well as the way in which we conduct our business. For example, the ACA was enacted into law in the U.S. in March 2010. The law imposed on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices, which includes certain products marketed and sold by us, as well as requiring research into the effectiveness of treatment modalities and instituting changes to the reimbursement and payment systems for patient treatments. In addition, governments and regulatory agencies continue to study and propose changes to the laws governing the clearance or approval, manufacture and marketing of medical devices, which could adversely affect our business and results of operations.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The FDA is currently exploring ways to modify its 510(k) clearance process. In addition, due to changes at the FDA in general, it has become increasingly more difficult to obtain 510(k) clearance as data requirements have increased. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. However, any changes could make it more difficult for us to maintain or attain clearance or approval to develop and commercialize our products and technologies.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government's role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially. In addition, if the excise taxes contained in the House or Senate health reform bills are enacted into law, our operating expenses resulting from such an excise tax and results of operations would be materially and adversely affected.

Our market acceptance in international markets requires regulatory approvals from foreign governments and may depend on third party reimbursement of participants' cost.

We have introduced our XTRAC and VTRAC products into markets in more than 30 countries in Europe, the Middle East, Asia, Australia, South Africa and parts of Central and South America through distributors. We cannot be certain that our salesforce and distributor network will be successful in marketing our products in these or other countries or that our distributors will purchase XTRAC or VTRAC systems beyond their current contractual obligations or in accordance with our expectations.

Even if we obtain and maintain the necessary foreign regulatory registrations or approvals, market acceptance of our products in international markets may be dependent, in part, upon the availability of reimbursement within applicable healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government-sponsored healthcare and private insurance. We may seek international reimbursement approvals for our products, but we cannot assure you that any such approvals will be obtained in a timely manner, if at all. Failure to receive international reimbursement approvals in any given market could have a material adverse effect on the acceptance or growth of our products in that market or others.

We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief. Our patents may also be subject to challenge on validity grounds, and our patent applications may be rejected.

Third parties could, in the future, assert infringement or misappropriation claims against us with respect to our current or future products. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties. Our potential competitors may assert that some aspect of our products infringes their patents. There also may be existing patents of which we are unaware that one or more components of our products may inadvertently infringe.

Any infringement or misappropriation claim could cause us to incur significant costs, could place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign the affected product to avoid infringement.

A court could order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

We rely on our patents, patent applications and other intellectual property rights to give us a competitive advantage. Whether a patent is valid, or whether a patent application should be granted, is a complex matter of science and law. Therefore we cannot be certain that, if challenged, our patents, patent applications and/or other intellectual property rights would be upheld. If one or more of those patents, patent applications and other intellectual property rights are invalidated, rejected or found unenforceable, those outcomes could reduce or eliminate any competitive advantage we might otherwise have had.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents or the patents of any of our future licensors. If we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, non-obviousness, adequate written description, clarity 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 U.S. Patent and Trademark Office (the "USPTO"), or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the claimed invention at issue on the grounds that our or our current or future collaboration partners' patent claims do not cover the claimed invention. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we were to establish infringement of our patent rights by a third party, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the market price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded and can involve substantial expenses. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority or inventorship of inventions with respect to our patents or patent applications or those of any of our future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation, interference proceedings, or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation and administrative proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

While we do not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, many healthcare laws and regulations apply to our business. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation and enforcement by both the federal government and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, as modified by the ACA, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services not provided as claimed and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as leading to regulations imposing certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The medical device industry has been under heightened scrutiny as the subject of government investigations and regulatory or legal enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If our operations or arrangements are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of its operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of these 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 against that action and the underlying alleged violations, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If the physicians or other providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

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

We and some of our third-party manufacturers and suppliers are required to comply with some or all of the FDA's Current Good Manufacturing Practices or its 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, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our manufacturers and suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market its 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 manufacturers and suppliers will be subject to additional future inspections. If our facilities or those of our manufacturers or suppliers 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 substantial 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 foreign 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 / 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 regulators. The FDA or state 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 we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with products, these products could be subject to restrictions or withdrawal from the market.

We are also subject to similar state requirements and licenses. Failure by us to comply with statutes and regulations administered by the FDA and other regulatory bodies, discovery of previously unknown problems with our products (including unanticipated adverse events or adverse events of unanticipated severity or frequency), manufacturing problems, or failure to comply with regulatory requirements, or failure to adequately respond to any FDA observations concerning these issues, could result in, among other things, any of the following actions:

- warning letters or untitled letters issued by the FDA;
- fines, civil penalties, injunctions and criminal prosecution;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawal or suspension of clearance or approval of our products by the FDA or other regulatory bodies;
- product recall or seizure;
- orders for physician or customer notification or device repair, replacement or refund;
- interruption of production; and
- operating restrictions.

If any of these actions were to occur, it would harm our reputation and adversely affect our business, financial condition and results of operations.

Our medical products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA has the authority to require the recall of commercialized medical device products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect its sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

Under the FDA medical device reporting 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. If we fail to report these events 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 financial results.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We have limited experience with acquiring other companies, products or product candidates, and limited experience with forming strategic alliances and collaborations. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliances or collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or equity securities as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

We may not be able to successfully integrate newly acquired businesses, joint ventures and other partnerships into our operations or achieve expected profitability from our acquisitions.

If we cannot successfully integrate acquisitions, joint ventures and other partnerships on a timely basis, we may be unable to generate sufficient revenue to offset acquisition costs, we may incur costs in excess of what we anticipate, and our expectations of future results of operations, including certain cost savings and synergies, may not be achieved. Acquisitions involve substantial risks, including:

- unforeseen difficulties in integrating operations, technologies, services, accounting and personnel;
- diversion of financial and management resources from existing operations;
- unforeseen difficulties related to entering geographic regions where we do not have prior experience;
- risks relating to obtaining sufficient equity or debt financing;
- potential loss of customers.

In addition, if we finance acquisitions by issuing equity securities or securities convertible into equity securities, our existing stockholders' interests would be diluted, which, in turn, could adversely impact the market price of our stock. Moreover, we could finance an acquisition with debt, resulting in higher leverage and interest costs.

If our actual liability for sales and use taxes is different from our accrued liability, it could have a material impact on our financial condition.

Included in accrued sales taxes and regulatory fees are certain estimated sales and use taxes and related penalties and interest to taxing authorities. We use estimates when accruing our sales and use tax liability, including interest and penalties. All of our tax positions are subject to audit. While we believe all of our estimates and assumptions are reasonable and will be sustained upon audit, actual liabilities and credits may differ significantly. If so, it may materially impact our financial condition, negatively if we underestimated our liability or positively if we overestimated our liability.

We may be subject to disruptions or failures in our information technology systems and network infrastructures, including through cyber-attacks or other third party breaches that could have a material adverse effect on our business.

We rely on the efficient and uninterrupted operation of complex information technology systems and network infrastructures to operate our business. We also hold data in various data center facilities upon which our business depends. A disruption, infiltration or failure of our information technology systems or any of our data centers as a result of software or hardware malfunctions, system implementations or upgrades, computer viruses, third-party security breaches, employee error, theft or misuse, malfeasance, power disruptions, natural disasters or accidents could cause breaches of data security, loss of intellectual property and critical data and the release and misappropriation of sensitive competitive information.

Further, data maintained in digital form is subject to risk of cyber-attacks, which are increasing in frequency and sophistication. Cyber-attacks could include the deployment of harmful malware and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. In addition, we do not have insurance coverage with respect to system failures or cyber-attacks.

While we have implemented a number of protective measures, including firewalls, antivirus, patches, data encryption, log monitors, routine back-ups with offsite retention of storage media, system audits, data partitioning, routine password modifications and disaster recovery procedures, such measures may not be adequate or implemented properly to prevent or fully address the adverse effect of such events. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

We have also outsourced significant elements of our information technology infrastructure and as a result we depend on third parties who are responsible for maintaining significant elements of our information technology systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by its employees, partners or vendors. These systems are also vulnerable to attacks by malicious third parties, and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, results of operations and financial condition.

Risks Relating to the December 30, 2015 Financing (the "Refinancing")

If we fail to abide by the terms and conditions of the Refinancing, the secured lenders have the right to proceed against our intellectual property and other assets pursuant to their first priority security interest.

On December 30, 2015, we entered into a $12.0 million credit facility pursuant to a Credit and Security Agreement (the "Security Agreement") and related financing documents with MidCap Financial Trust ("MidCap") and the lenders listed in the loan documents. We have drawn down the full $12.0 million available to us. Our obligations under the credit facility are secured by a first priority lien on all of our assets. Our commitments under the Security Agreement require that we maintain our listing on a nationally recognized stock exchange and that we meet certain rolling 12-month revenue milestones. We have amended the Security Agreement four times, and pursuant to the fourth amendment the terms have been amended to impose less restrictive covenants on us and to lower prepayment and exit fees and from the proceeds of the financing we paid MidCap $3.0 million in principal and an additional amount in associated fees. Our failure to abide by our on-going obligations under the loan documents could result in the lender seeking to foreclose on our assets.

Risks Relating to Our Common Stock

As a result of a financing in June 2015 we incurred significant debt in the form of convertible preferred stock. In order to repay the underlying debt and help make our stock more liquid, we entered into an exchange agreement with holders of the debt and issued them a new class of preferred shares. These preferred shares present significant dilution risk for our shareholders.

On September 20, 2017, we announced the closing of an exchange transaction pursuant to the Securities Exchange Agreement (the "Exchange Agreement") dated as of June 7, 2017 between us and holders of our 2.25% Senior Series A Secured Convertible Debentures due June 30, 2021 and 4% Senior Secured Convertible Debentures due July 30, 2021 (collectively, the "Debentures"). In closing the exchange transaction under the Exchange Agreement, the holders of the Debentures exchanged the Debentures, having an aggregate principal amount of approximately $40.5 million, into 40,482 shares (the "Preferred Shares") of our newly created Series C Convertible Preferred Stock. The Preferred Shares are convertible into a total of approximately 15,049,000 shares of our common stock. Each Preferred Share has a stated value of $1,000 and is convertible into shares of common stock at a conversion price equal to $2.69. We included the Exchange Agreement as an exhibit to our Form 8-K current report, which was filed with the SEC on June 7, 2017. We relied upon the exemption from registration under the Securities Act of 1933 (the "Securities Act") afforded by Section 3(a)(9) of the Securities Act, i.e., the exchange of the Debentures for the Preferred Shares in which no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange. In connection with the closing under the Exchange Agreement, on September 20, 2017, we filed a Certificate of Designations with the Delaware Secretary of State setting forth the rights, preferences and privileges of the Company's Series C Convertible Preferred Stock. As of June 27, 2018, Preferred Shares that are convertible into approximately 3.8 million shares of common stock remain outstanding.

Our largest stockholder, Accelmed, has the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of September 10, 2018, Accelmed beneficially owns approximately 40% of our outstanding voting stock. As a result, Accelmed would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Accelmed would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

If we fail to maintain the adequacy of our internal controls, our ability to provide accurate financial statements could be impaired and any failure to maintain our internal controls could have an adverse effect on our stock price.

The Sarbanes-Oxley Act of 2002 ("SOX"), as well as rules implemented by the SEC, the Public Company Accounting Oversight Board and the Nasdaq Stock Market, have required changes in the corporate governance practices of public companies. Monitoring compliance with the existing rules and implementing changes required by these rules is expensive and may increase our legal and financial compliance costs, divert management attention from operations and strategic opportunities, and make legal, accounting and administrative activities more time-consuming. Since 2008, we have retained a consultant experienced in SOX that assists us in the process of instituting changes to our internal procedures to satisfy the requirements of SOX. We have evaluated our internal control systems in order to allow us to report on our internal controls, as required by Section 404 of the SOX. As a small company with limited capital and human resources, we may need to divert management's time and attention away from our business in order to ensure continued compliance with these regulatory requirements. We may require new information technologies systems, the auditing of our internal controls, and compliance training for our directors, officers and personnel. Such efforts may entail a significant expense. If we fail to maintain the adequacy of our internal controls as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of SOX. Any failure to maintain the adequacy of our internal controls could have an adverse effect on timely and accurate financial reporting and the trading price of our common stock.

Our stock price may be volatile, meaning purchasers of our common stock could incur substantial losses.

Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:

- failure of any of our products to achieve or continue to have commercial success;
- the timing of regulatory approval for our future products;
- adverse regulatory determinations with respect to our existing products;
- results of our research and development efforts and our clinical trials;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the U.S. and foreign countries;
- our ability to manufacture our products to commercial standards;
- developments concerning our clinical collaborators, suppliers or marketing partners;
- changes in financial estimates or recommendations by securities analysts;
- public concern over our products;
- developments or disputes concerning patents or other intellectual property rights;
- product liability claims and litigation against us or our competitors;
- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of third-party reimbursement in the U.S. and other countries;
- changes in accounting principles or practices;
- general economic, industry and market conditions; and
- future sales of our common stock.

A decline in the market price of our common stock could cause you to lose some or all of your investment, limit your ability to sell your shares of stock and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders have, and may in the future, initiate securities class action lawsuits if the market price of our stock drops significantly. Whether or not meritorious, litigation brought against us could result in substantial costs and could divert the time and attention of our management. Our insurance to cover claims of this sort may not be adequate.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of our stock.

Provisions of our restated certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our board of directors. These provisions:

- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- do not permit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors the ability to designate the terms of and issue a new series of preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law generally limits our ability to engage in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock. Further, our bylaws provide that any transaction between us and Accelmed or its affiliates must be approved by either (i) the vote of the holders of a majority of shares of our Non-Affiliated Stock (defined as the voting stock not held by Accelmed or its affiliates) or (ii) by an independent committee of the Board of Directors.

These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. You can identify these statements by the fact that they do not relate strictly to historic or current facts. They use words, such as "anticipate," "could," "continue," "contemplate," "estimate," "expect," "will," "may," "potential," "intend," "plan," "believe," and other words and terms of similar meaning. These include statements, among others, relating to the sufficiency of our financial resources, our planned future actions, and expected outcomes, our products under development, our intellectual property position, our plans with respect to funding operations, projected expense levels, and the outcome of contingencies.

Any or all of our forward-looking statements in this report may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Consequently, no forward-looking statement can be guaranteed. Actual results may vary materially from those set forth in forward-looking statements. The uncertainties that may cause differences include, but are not limited to: uncertainty of forecasts of future business performance, consumer trends and macro-economic conditions; uncertainty of our estimates regarding the sufficiency of our cash resources, expenses, capital requirements and needs for additional financing and our ability to obtain additional financing; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; our ability to obtain and maintain regulatory approvals of our products; anticipated results of existing or future litigation; and descriptions or assumptions underlying or related to any of the above items.

We will not update forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. You are advised to consult any further disclosures we make in our reports to the SEC, including our reports on Forms 10-K, 10-Q and 8-K. Our filings list various important factors that could cause actual results to differ materially from expected results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

USE OF PROCEEDS

We are not selling any securities in this offering and we will not receive any of the proceeds from the sale of shares of our Common Stock by the selling securityholders. The selling securityholders will receive all of the proceeds from any sales of the shares of our Common Stock offered hereby. However, we will incur expenses in connection with the registration of the shares of our Common Stock offered hereby, including legal and accounting fees.

SELLING SECURITYHOLDERS

The shares of Common Stock being offered by the selling securityholders are those issued to the selling securityholders pursuant to the Agreements. We are registering 15,893,745 shares of Common Stock. The shares of Common Stock were issued by the Company to accredited investors pursuant to or in connection with the Agreements.

The table below lists the selling securityholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) of the shares of Common Stock held by each of the selling securityholders. The second column lists the number of shares of Common Stock beneficially owned by the selling securityholders, based on their respective ownership of shares of Common Stock, as of September 10, 2018. The percentage of shares beneficially owned prior to the offering is based on 29,943,086 shares of our Common Stock outstanding as of September 10, 2018. The number of shares in the column "Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus" represents all of the shares that the selling securityholder may offer under this prospectus and does not take into account any limitations in the Agreements.

The selling securityholders may sell all, some or none of their shares in this offering. See "Plan of Distribution."

Name of Selling Security Holder	Shares of Common Stock Beneficially Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Shares of Common Stock Beneficially Owned After Offering (1)	Percentage of Shares of Common Stock Beneficially Owned After Offering (1)
Accelmed Growth Partners L.P. (2)	12,120,679	12,112,627	8,052	*
Broadfin Healthcare Master Fund, Ltd. (3)	7,231,583	967,685	6,263,898	9.99%
Sabby Healthcare Master Fund, Ltd. (4)	1,205,751	236,443	969,308	3.14%
Sabby Volatility Warrant Master Fund, Ltd. (5)	964,933	713,510	251,423	*
Gohan Investments, Ltd. (6)	931,740	931,740	-	*
Dr. Dolev Rafaeli (7)	1,168,496	931,740	236,756	*

* Less than 1%.

(1) Assumes the sale of the maximum number of shares of Common Stock to be sold pursuant to this prospectus.

(2) The business address of Accelmed Growth Partners L.P. ("Accelmed") is 6 Hachochlim Street, 6th floor, Herzliya Pituach L3 46120 Israel. Accelmed Growth Partners GP ("Accelmed GP"), the General Partner of Accelmed, and Uri Geiger, the Managing Director of Accelmed Growth Partners Management Ltd., which is the management company of Accelmed, each have voting and investment control of the securities held by Accelmed. Each of Accelmed GP and Uri Geiger disclaim beneficial ownership over the securities owned by Accelmed except to the extent of their respective pecuniary interest therein. Accelmed holds 12,112,627 shares of common stock. Uri Geiger also holds restricted stock units to purchase 8,052 shares of common stock exercisable within 60 days of September 10, 2018.

(3) The business address of Broadfin Healthcare Master Fund, Ltd. ("Broadfin") is 20 Genesis Close Ansbacher House, Second Floor, P.O. Box 1344, Grand Cayman KY1-1108, Cayman Islands and the business address of each of Broadfin Capital, LLC and Kevin Kotler is 300 Park Avenue, 25th Floor, New York, New York 10022. Broadfin, Broadfin Capital, LLC and Kevin Kotler have shared voting and investment control of the securities held by Broadfin. Broadfin holds the following securities: 2,885,578 shares of common stock, (ii) 640,057 shares of common stock issuable upon the exercise of warrants held by Broadfin and (iii) 3,705,948 shares of common stock issuable upon conversion of 9,969 shares of Series C Preferred Stock. The ownership of Broadfin is subject to a 9.99% ownership blocker, pursuant to which shares of our common stock may not be issued pursuant to the conversion of Series C Preferred Stock, to the extent such issuance would cause Broadfin to beneficially own more than 9.99% of our outstanding common stock. The share ownership numbers for Broadfin in the table above do not reflect this 9.99% blocker.

(4) The business address of Sabby Healthcare Master Fund Ltd. ("Sabby HMF") is c/o Sabby Management LLC, 10 Mountainview Road, Suite 205, Upper Saddle River, NJ 07458. Sabby Management, LLC serves as the investment manager of Sabby HMF. Hal Mintz is the manager of Sabby Management, LLC and has voting and investment control of the securities held by Sabby HMF. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities beneficially owned by Sabby HMF except to the extent of their respective pecuniary interest therein. Sabby HMF holds the following securities: (i) 236,443 shares of common stock and (ii) 969,308 shares of common stock issuable upon the exercise of warrants held by Sabby HMF.

(5) The business address of Sabby Volatility Warrant Master Fund Ltd. ("Sabby VWMF") is c/o Sabby Management LLC, 10 Mountainview Road, Suite 205, Upper Saddle River, NJ 07458. Sabby Management, LLC serves as the investment manager of Sabby VWMF. Hal Mintz is the manager of Sabby Management, LLC and has voting and investment control of the securities held by Sabby VWMF. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities beneficially owned by Sabby VWMF except to the extent of their respective pecuniary interest therein. Sabby VWMF holds the following securities: (i) 713,510 shares of common stock and (ii) 251,423 shares of common stock issuable upon the exercise of warrants held by Sabby VWMF.

(6) The business address of Gohan Investments, Ltd. ("Gohan") is 66 Pinkas St. #161 Tel Aviv 62157, Israel. Yoav Ben Dror is the principal of Gohan and has voting and investment control of the securities held by Gohan. Ben Dror disclaims beneficial ownership over the securities beneficially owned by Gohan except to the extent of his pecuniary interest therein. Gohan holds 931,740 shares of common stock.

(7) Dr. Rafaeli's address is 5 Lambs Lane, Cresskill, New Jersey 07626. Dr. Rafeli holds 931,740 shares of common stock and options to purchase 236,756 shares of common stock exercisable within 60 days of September 10, 2018.

PLAN OF DISTRIBUTION

We are registering the shares of Common Stock that were issued pursuant to the Agreements to permit the resale of these shares of Common Stock by the holders of such shares of Common Stock from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of Common Stock. We will bear all fees and expenses incident to our obligation to register the shares of Common Stock.

The selling stockholders may sell all or a portion of the shares of Common Stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of Common Stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of Common Stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144;
- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the selling stockholders effect such transactions by selling shares of Common Stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of Common Stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of Common Stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of Common Stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of Common Stock short and deliver shares of Common Stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of Common Stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of Common Stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer participating in the distribution of the shares of Common Stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of Common Stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of Common Stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers.

Under the securities laws of some states, the shares of Common Stock may be sold in such states only through registered or licensed brokers or dealers.

There can be no assurance that any selling stockholder will sell any or all of the shares of Common Stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of Common Stock by the selling stockholders and any other participating person. All of the foregoing may affect the marketability of the shares of Common Stock.

We will pay all expenses of the registration of the shares of Common Stock pursuant to the Registration Rights Agreement, estimated to be $34,208.03 in total, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that a selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the Registration Rights Agreement, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the Registration Rights Agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

LEGAL MATTERS

The validity of the securities we are offering will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

EXPERTS

The consolidated balance sheets of STRATA Skin Sciences, Inc. and Subsidiary as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years then ended, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated by reference. Such financial statements have been incorporated by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a public company and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's Public Reference Room at Station Place, 100 F Street, N.E., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. Our SEC filings are also available to the public at the SEC's web site at www.sec.gov, and on our web site at www.strataskinsciences.com. The information contained on our web site is not included or incorporated by reference into this prospectus. In addition, our Common Stock is listed for trading on The Nasdaq Capital Market under the symbol "SSKN."

This prospectus is only part of a Registration Statement on Form S-3 that we have filed with the SEC under the Securities Act, and therefore omits certain information contained in the Registration Statement. We have also filed exhibits and schedules with the Registration Statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may:

- inspect a copy of the Registration Statement, including the exhibits and schedules, without charge at the Public Reference Room,
- obtain a copy from the SEC upon payment of the fees prescribed by the SEC, or
- obtain a copy from the SEC's web site or our web site.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus and information we file later with the SEC will automatically update and supersede this information. We incorporate by reference into this prospectus the documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (1) after the date of this prospectus and prior to the time that we sell all of the securities offered by this prospectus or the earlier termination of the offering, and (2) after the date of the initial registration statement of which this prospectus forms a part and prior to the effectiveness of the registration statement (except in each case the information contained in such documents to the extent "furnished" and not "filed"). The documents we are incorporating by reference as of their respective dates of filing are (unless otherwise indicated the File No. for each of the below filings is 001-51481):

- Our Annual Report on Form 10-K for the year ended December 31, 2017, filed on April 2, 2018;
- Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018, filed on May 15, 2018 and August 14, 2018 respectively;
- Our Current Reports on Form 8-K filed on April 2, 2018 (Accession No. 0001051514-18-000008), May 15, 2018, May 23, 2018 and May 29, 2018 (except for such information furnished under Item 7.01 and the exhibits furnished thereto); and
- The description of our securities contained in our Registration Statement on Form 8-A filed on August 8, 2005 pursuant to Section 12(g) of the Exchange Act, and any amendment or report filed with the SEC for purposes of updating such description.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost, by contacting STRATA Skin Sciences, Inc., 100 Lakeside Drive, Suite 100, Horsham, Pennsylvania, Attention: Investor Relations. The Company can be reached via telephone at (215) 619-3200.

STRATA Skin Sciences, Inc.

15,893,745 Shares of Common Stock

PROSPECTUS

SEPTEMBER 24, 2018