

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 0-11635

STRATA SKIN SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of
incorporation or Organization)

13-3986004

(I.R.S. Employer
Identification No.)

5 Walnut Grove Drive, Suite 140 Horsham, Pennsylvania

(Address of principal executive offices)

19044

(Zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name Of Each Exchange On Which Registered
Common Stock, \$0.001 Par Value	SSKN	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.0405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
Emerging growth company

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares outstanding of our common stock as of June 30, 2023 was 34,881,453 shares. The aggregate market value of voting and non-voting common equity held by non-affiliates on the registrant was \$17,264,756, computed by reference to the closing market price of \$0.95 of the common stock as of June 30, 2023 and 18,173,427 shares held by non-affiliates. As of March 20, 2024, the number of shares outstanding of our common stock was 35,060,920.

Documents incorporated by reference:

Portions of the proxy statement relating to STRATA Skin Sciences, Inc.'s 2024 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the “Annual Report”), including the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements relate to, among others, our plans, objectives and expectations for our business, operations and financial performance and condition, and can be identified by terminology such as “may,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “will,” “could,” “project,” “target,” “potential,” “continue” and similar expressions that do not relate solely to historical matters. Forward-looking statements are based on management’s belief and assumptions and on information currently available to management. Although we believe that the expectations reflected in forward-looking statements are reasonable, such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- forecasts of future business performance, consumer trends and macro-economic conditions;
- descriptions of market, competitive conditions, and competitive product introductions;
- descriptions of plans or objectives of management for future operations, products or services;
- actions by the FDA or other regulatory agencies with respect to our products or product candidates;
- changes to third-party reimbursement of laser treatments using our devices;
- 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;
- anticipated results of existing or future litigation or government actions;
- health emergencies, the spread of infectious disease or pandemics; and
- descriptions or assumptions underlying or related to any of the above items.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Annual Report, even if subsequently made available by us on our website or otherwise. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. You should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

You should read this Annual Report and the documents that we reference in this Annual Report as exhibits with the understanding that our actual future results, performance, and events and circumstances may be materially different from what we expect.

PART I

ITEM 1. BUSINESS

Our Company

Overview

We are a medical technology company in dermatology dedicated to developing, commercializing and marketing innovative products for the treatment of dermatologic conditions. Our products include the XTRAC® and now Pharos® excimer lasers and VTRAC® lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions. Our products also include the TheraClear® Acne Therapy System utilized in the treatment of mild to moderate inflammatory, comedonal and pustular acne.

Corporate Overview

We were incorporated in the State of New York in 1989 under the name Electro-Optical Sciences, Inc. and subsequently reincorporated under the laws of the State of Delaware in 1997. In April 2010, we changed our name to MELA Sciences, Inc. In June 2015, we completed the acquisition of the XTRAC® Excimer Laser and the VTRAC® excimer lamp businesses from PhotoMedex, Inc. (the “Acquisition”). Prior to the Acquisition, the Company’s only product was the MelaFind® system, or MelaFind, a device for aiding dermatologists in the evaluation of clinically atypical pigmented skin lesions. On January 5, 2016, we changed our name to STRATA Skin Sciences, Inc., and we have discontinued the MelaFind business.

In August 2021 and January 2022, we acquired the Pharos U.S. dermatology business and the TheraClear acne treatment business, respectively.

Post-COVID-19 Pandemic

Since March 2020, the global pandemic related to a new strain of coronavirus (“COVID-19”) has negatively impacted business conditions in the industry in which we operate, disrupted global supply chains, constrained workforce participation and created significant volatility and disruption of financial markets. The pandemic led to the suspension of elective procedures in the U.S. and to the temporary closure of many physician practices, which are our primary customers. While most offices have reopened, some physician practices closed and never reopened. Accordingly, the COVID-19 pandemic and its variants have negatively impacted our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frames and those of our primary customers. It has also negatively impacted our supply chains and transport, customer behavior and staffing.

Impact of Russia-Ukraine War

Prior to the outbreak of the Russia-Ukraine War, Ukraine was the largest exporter of noble gases including neon, krypton, and xenon and has historically been the source of a significant amount of gas supplied to us by our contract suppliers. Neon gas is essential to the proper functioning of our lasers. Our suppliers have been resourceful in continuing to supply gases to us but cannot assure us that the supply will not remain uninterrupted. The reduced supply and ongoing conflict have also impacted the price of gas worldwide. Additionally, the Creating Helpful Incentives to Produce Semiconductors and Science Act of 2022 has led to a further tightening of rare gas supplies as semiconductor chip manufacturers reconfigure their supply chains to address the need to secure their own supplies of rare gases for use in the manufacture of computer chips.

XTRAC and Pharos Systems and VTRAC Systems

The XTRAC and Pharos excimer laser technology emits highly concentrated UV light targeted primarily towards autoimmune dermatological skin disorders such as psoriasis, vitiligo, atopic dermatitis, and eczema, among others. The XTRAC system received U.S. Food and Drug Administration (“FDA”) clearance in 2000 and the Pharos system in 2004, and excimer laser has since become a widely recognized treatment for psoriasis, vitiligo and other skin diseases. Psoriasis and vitiligo alone affect up to 13 million people in the U.S. and 195 million people worldwide. VTRAC is a UV light lamp system that works in much the same way as the XTRAC. It received FDA clearance in August 2005 and Conformité Européenne (“CE”) mark approval in January 2006 and has been marketed exclusively in international markets.

Present in natural sunlight, ultraviolet B (“UVB”) is an accepted psoriasis treatment that penetrates the skin to slow the growth of damaged skin cells thereby placing the disease into remission for a period of time. Studies have shown that the remission time can last three to six months or longer. In our XTRAC system, our targeted therapy approach delivers optimum amounts of UVB light directly to skin lesions, sparing healthy tissue. Many peer reviewed studies have proven that the XTRAC excimer laser can clear psoriasis faster and produce longer remissions than other UVB modalities, resulting in fewer treatments to produce the desired result.

We currently market four XTRAC excimer models. In October 2018, we announced the launch of XTRAC S3®, which, as compared to previous XTRAC generations, is smaller, faster and has a new user interface. In January 2020, we announced the FDA granted clearance for our XTRAC Momentum Excimer Laser System platform. This clearance is the first full platform clearance since 2008. Momentum has an increased power range to improve patient safety and treatment efficiency; a new and exclusive proprietary short-hair tip, providing ease of use in difficult-to-treat scalp psoriasis; and an enhanced user interface and database. In February 2022, we announced the commercial launch of our next generation excimer laser system, XTRAC Momentum® 1.0, which delivers higher power and a faster repetition rate than the current models, along with a new user interface and slim design. We continue to market the XTRAC Velocity, our third-generation laser and the XTRAC Ultra Plus, which is also a highly effective model marketed primarily in certain international markets. The Momentum, S3, Velocity and the Ultra Plus are capable of treating mild, moderate and severe psoriasis, vitiligo, atopic dermatitis and leukoderma.

The XTRAC excimer laser is marketed in the U.S. mainly under a recurring revenue model in which we place the system in the physician’s office for no upfront charge and generate our revenue on a per-use basis (referred to herein as the dermatology recurring procedures model or segment). We estimate that there are over 1,000 XTRAC lasers in use in the U.S., of which 923 systems were, as of December 31, 2023, included in our dermatology recurring procedures revenue model. The Pharos business we acquired in 2021 provides us with the opportunity to convert the Pharos customer base to our XTRAC excimer laser system. The target U.S. audience for XTRAC lasers comprises approximately 3,500 dermatologists who perform disease management. Until 2019, in markets outside the U.S. the XTRAC laser had been marketed primarily as dermatology procedures equipment sales through distributors in over twenty-five countries. The VTRAC is marketed exclusively in international markets through the same distributors.

Since 2019, we have been transitioning our international dermatology procedures equipment sales through our master distributor to a direct distribution model for equipment sales and recurring revenue on a country by country basis. In January 2022, our agreement with our master distributor expired. We have signed distributor contracts by year as follows: 2019 – Korea, 2020 – Japan, 2021 – China, Israel, Saudi Arabia, Kuwait, Oman, Qatar, Bahrain, UAE, Jordan, Iraq and 2023 – Mexico, India.

Studies have concluded that XTRAC treatment leads to significant improvement in psoriasis plaques and severity scores in as few as six to ten treatments. Treatment protocols recommend that patients receive two treatments per week with a minimum of 48 hours between treatments. Our data shows that treatment with XTRAC excimer lasers has an 89% efficacy rate and produces only minimal side effects. In support of its clinical effect, the XTRAC excimer lasers have been cited in over 45 clinical studies and research programs, with findings published in peer-reviewed medical journals around the world. The XTRAC excimer laser has also been endorsed by the National Psoriasis Foundation, and its use for psoriasis is covered by nearly all major insurance companies, including Medicare. XTRAC treatment is a reimbursable procedure for psoriasis under three Current Procedural Terminology (“CPT”) codes that differ based on the total skin surface area being treated. Insurance Reimbursement to physicians varies based upon insurance company and location. The national CPT code reimbursement established by the Center for Medicaid Services (“CMS”), which forms the basis for most insurance companies’ reimbursement levels, ranges for the three codes between \$153 per treatment to \$228 per treatment. (See “Third Party Reimbursement” below.)

Psoriasis, the Disease

The World Health Organization describes psoriasis as a chronic, noncommunicable, painful, disfiguring and disabling disease for which there is no cure, and which generates a great negative impact on patients' quality of life. It manifests itself in many forms and typically causes raised, red, scaly patches that appear on the skin and may cause itchiness, burning or stinging. Psoriasis is also associated with other serious health conditions such as diabetes, heart disease and depression.

Psoriasis Treatment Options

There are essentially three main types of psoriasis treatments, as listed below:

Topical therapies: These can include corticosteroids, vitamin D3 derivatives, coal tar, anthralin and retinoids, among others, that are sold as a cream, gel, liquid, spray, or ointment. The efficacy of topical agents varies from person to person, although these products are commonly associated with a loss of potency over time as people develop resistance.

Phototherapy: This is the area in which we operate. Our XTRAC Excimer Systems are FDA-cleared, reimbursed by insurance, and exhibit none of the significant side-effects associated with some alternative therapies.

Systemic medications: There are a number of prescription medications available for psoriasis, which are given either by mouth or as an injection. The popularity and use of these medications are growing significantly, notwithstanding their cost and their potentially severe side-effects.

XTRAC excimer lasers are particularly significant and beneficial for mild to moderate psoriasis patients who prefer a noninvasive treatment approach without the side effects of invasive, systemic agents, or to patients who have developed a resistance to topical agents. In many cases, patients treated with topical or systemic therapies are also candidates for phototherapy.

Using the XTRAC and Pharos Excimer Lasers to Treat Vitiligo and Other Skin Diseases

UV light therapy is considered to be an effective and safe treatment for many skin disorders beyond psoriasis. To this effect, the XTRAC technology is FDA cleared for the treatment of not only psoriasis but also vitiligo (a skin pigment deficiency), atopic dermatitis (eczema) and leukoderma, which is a localized loss of skin pigmentation that occurs after an inflammatory skin condition such as a burn, intralesional steroid injection, or post dermabrasion.

XTRAC technology for vitiligo patients typically requires more therapy sessions than for psoriasis but is dependent on the severity of the disease. In the treatment of vitiligo, we believe the XTRAC functions to reactivate the skin's melanocytes (the cells that produce melanin), which causes pigment to return. To date, there is not sufficient data to confirm how long patients can expect their vitiligo to be in remission after XTRAC therapy. Based on anecdotal reports, we believe that re-pigmentation may last for several years. Historically, vitiligo treatments had been considered cosmetic procedures by insurance companies, and as such were not reimbursed. However, over the past several years, there has been a significant increase in insurance coverage for these procedures and we estimate that as of December 31, 2023, approximately 76% of insurers consider XTRAC treatments to be medically necessary for the treatment of vitiligo and therefore provide coverage. Recent changes to CPT code descriptions may impact the extent of this coverage in the future.

We believe that several factors have limited the growth of the use of XTRAC treatments for those who suffer from psoriasis and vitiligo. Specifically, we believe that awareness of the positive effects of XTRAC treatments has not been high enough among both sufferers and providers; and that the treatment regimen requiring sometimes up to 12 or more treatments has limited XTRAC use to certain patient populations. Addressing the lack of knowledge issue, we have a direct to patient advertising campaign aimed at motivating psoriasis and vitiligo patients to seek out XTRAC treatments from our physician partners. Specific advertisements encourage prospective patients to contact our patient advocacy center via telephone or web site, wherein we provide information on the treatment and insurance coverage, and ultimately we can schedule an appointment for the prospective patient to be evaluated by a physician within our customer network, convenient to their location, to determine if they would benefit from XTRAC treatments.

STRATAPEN

In January 2017, we entered into an OEM agreement with Esthetic Education, LLC to private label the STRATAPEN device. STRATAPEN® MicroSystems is a micropigmentation device that provides advanced technology offering exceptional results. This contract expired in January 2020, and we continued to sell parts and accessories through January 1, 2024. The Company no longer offers the device or accessories.

TheraClear

In January 2022, we acquired the TheraClear assets from Theravant Corporation. The TheraClear Acne Therapy System delivers a two-part process for treating inflammatory acne, pustular acne and comedonal acne that combines a vacuum and broadband light that has been proven to clear skin rapidly for fast and visible reduction in acne and associated redness. Treatments are very comfortable, take 10 minutes to perform, are highly effective, and can be used on all skin types.

Competition

Our XTRAC product line competes with pharmaceutical compounds and methodologies used to treat an array of skin conditions. Such alternative treatments may be in the form of topical products, systemic medications, and phototherapies from both large pharmaceutical and smaller devices companies. Our major competitors for dermatological solutions include The Daavlin Company, National Biologic Corporation, and pharmaceutical companies producing topical products and systemic and biologic medications. Currently, our XTRAC system is believed to be a competitive therapy to alternative treatments on the basis of its recognized clinical effect, minimal side effect profile, cost-effectiveness and reimbursement.

Our TheraClear device competes with a range of over the counter treatment methodologies, as well as prescription only medications, and in-office treatment methodologies.

Manufacturing

We manufacture our XTRAC products at our 17,000 sq. ft. facility in Carlsbad, California. Our California facility is certified as ISO 13485 compliant. ISO 13485 is an International standardization written by the International Organization for Standardization, which publishes requirements for a comprehensive quality management system for the design and manufacture of medical devices. Certification to the standard is awarded by accredited third parties. We maintain third-party relationships for the manufacture and/or maintenance of our Pharos and TheraClear systems. We believe that our present manufacturing capacity at these facilities is sufficient to meet foreseeable demand for our products.

Research and Development Efforts

Our research and development team, including engineers, consists of approximately four employees. We conduct research and development activities at our facility located in Carlsbad, California. Our research and development efforts are focused on the application of our XTRAC system for the treatment of inflammatory skin disorders.

Intellectual Property

Our policy is to protect our intellectual property by obtaining U.S. and foreign patents to protect technology, inventions and improvements important to the development of our business. As of December 31, 2023, 24 issued U.S. patents are in force or pending, several of these patents have foreign counterparts issued and pending, and 15 patents are related to the discontinued MelaFind product.

We also rely on trade secrets and technical know-how in the manufacture and marketing of our products. We require our employees, consultants and contractors to execute confidentiality agreements with respect to our proprietary information.

In February 2021, the license for the exclusive rights for patents related to the delivery of treatment to vitiligo with the Icahn School of Medicine at Mount Sinai expired. We do not believe that this will have a material impact on our business.

We believe that our patented methods and apparatus, together with proprietary trade-secret technology and registered trademarks, give us a competitive advantage; however, whether a patent is infringed or is valid, or whether or not a patent application should be granted, are all complex matters of science and law, and therefore, we cannot be certain that, if challenged, our patented methods and apparatus and/or trade-secret technology would be upheld. If one or more of our patented methods, patented apparatus or trade-secret technology rights, or our trademark rights, are invalidated, rejected or found unenforceable, that could reduce or eliminate any competitive advantage we might otherwise have had.

Government Regulation

Regulations Relating to Products and Manufacturing

Our products and research and development activities are regulated by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. Any medical device or cosmetic we manufacture and/or distribute will be subject to pervasive and continuing regulation by the FDA. The U.S. Food, Drug and Cosmetics Act, or FD&C Act, and other federal and state laws and regulations govern the pre-clinical and clinical testing, design, manufacture, use, labeling and promotion of medical devices, including our XTRAC, VTRAC, and TheraClear devices. Product development and approval for medical devices within this regulatory framework takes a number of years and involves the expenditure of substantial resources.

In the U.S., medical devices are classified into three different classes, Class I, II and III, on the basis of controls deemed necessary to provide a reasonable assurance of the safety and effectiveness of the device. Class I devices are subject to general controls, such as facility registration, medical device listing, labeling requirements, premarket notification (unless the medical device has been specifically exempted from this requirement), adherence to the FDA's Quality System Regulation, and requirements concerning the submission of device-related adverse event reports to the FDA. Class II devices are subject to general and special controls, such as performance standards, premarket notification (510(k) clearance), post-market surveillance, and FDA Quality System Regulations. Generally, Class III devices are those that must receive premarket approval by the FDA to provide a reasonable assurance of their safety and effectiveness, such as life-sustaining, life-supporting and implantable devices, or new devices that have been found not to be substantially equivalent to existing legally marketed devices. Both XTRAC and TheraClear are Class II devices.

With limited exceptions, before a new medical device can be distributed in the U.S., marketing authorization typically must be obtained from the FDA through a premarket notification under Section 510(k) of the FD&C Act, or through a premarket approval application under Section 515 of the FD&C Act. The FDA will typically grant a 510(k) clearance if it can be established that the device is substantially equivalent to a predicate device that is a legally marketed Class I or II device (or to pre-amendments Class III devices for which the FDA has yet to call for premarket approvals). We have received FDA 510(k) clearance to market our XTRAC and VTRAC systems for the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. The FDA granted these clearances under Section 510(k) on the basis of substantial equivalence to other technologies that had received prior clearances.

For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or effectiveness of the device, or that constitute a major change in the intended use of the device, will require a new 510(k) submission. In August 2003 the FDA granted 510(k) clearance for a significantly modified version of our XTRAC laser, which we have marketed as the XTRAC XL Plus Excimer Laser System. In October 2004 the FDA granted clearance for the XTRAC Ultra (AL 8000) Excimer Laser System and, in March 2008 we received 510(k) clearance for the XTRAC Velocity (AL 10000) Excimer Laser System. These approvals were originally granted to PhotoMedex, Inc. and acquired by us in the June 2015 acquisition described above. In January 2020, we announced the FDA granted clearance of our XTRAC Momentum Excimer Laser platform.

The TheraClear device has been cleared by the FDA through the 510(k) process.

We are subject to routine inspection by the FDA and, as noted above, must comply with a number of regulatory requirements applicable to firms that manufacture medical devices and other FDA-regulated products for distribution within the U.S., including requirements related to device labeling (including prohibitions against promoting products for unapproved or off-label uses), facility registration, medical device listing, adherence to the FDA's Quality System Regulation, good manufacturing processes and requirements for the submission of reports regarding certain device-related adverse events to the FDA.

We are also subject to the radiological health provisions of the FD&C Act and the general and laser-specific radiation safety regulations administered by the Center for Devices and Radiological Health, or CDRH, of the FDA. These regulations require laser manufacturers to file initial, new product, supplemental and annual reports, to maintain quality control, product testing and sales records, to incorporate certain design and operating features (depending on the class of product) in lasers sold to end users pursuant to a performance standard and to certify and appropriately label each laser sold as belonging to one of four classes, based on the level of radiation from the laser that is accessible to users. Moreover, we are obligated to repair, replace, or refund the cost of certain electronic products that are found to fail to comply with applicable federal standards or otherwise are found to be defective. The CDRH is empowered to seek fines and other remedies for violations of the regulatory requirements. To date, we have filed the documentation with the CDRH for our laser products requiring such filing and have not experienced any difficulties or incurred significant costs in complying with such regulations.

We are approved by the European Union to affix the CE mark to our XTRAC laser and VTRAC lamp systems. This certification is a mandatory conformity mark for products placed on the market in the European Economic Area, which is evidence that they meet all European Community, or EC, quality assurance standards and compliance with applicable European medical device directives for the production of medical devices. This will enable us to market our approved products in all of the member countries that accept the CE mark. We also are required to comply with additional individual national requirements that are in addition to those required by these nations. Our products have also met the requirements for marketing in various other countries.

Our TheraClear device is being manufactured for us by a third party, who is subject to the same regulations. We rely on the manufacturer to ensure compliance with the regulations. Failure to comply with applicable regulatory requirements can result in fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspensions of production, refusals by the U.S. and foreign governments to permit product sales and criminal prosecution. We are, or may become, subject to various other federal, state, local and foreign laws, regulations and policies relating to, among other things, safe working conditions, good laboratory practices and the use and disposal of hazardous or potentially hazardous substances used in connection with research and development.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws whose purpose is to eliminate fraud and abuse in federal health care programs. Our business is subject to compliance with these laws.

Anti-Kickback Laws

In the U.S., there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. The U.S. federal healthcare programs' Anti-Kickback Statute makes it unlawful for individuals or entities knowingly and willfully to solicit, offer, receive or pay any kickback, bribe or other remuneration, directly or indirectly, in exchange for or to induce the purchase, lease or order, or arranging for or recommending purchasing, leasing, or ordering, any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program such as Medicare or Medicaid. The Anti-Kickback Statute covers "any remuneration," which has been broadly interpreted to include anything of value, including for example gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the arrangement can be found to violate the statute. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, several courts have permitted kickback cases brought under the Federal False Claims Act to proceed, as discussed in more detail below.

The reach of the Anti-Kickback Statute was broadened by the Patient Protection and Affordable Care Act of 2010 (the “ACA”), which, among other things, amends the intent requirement of the federal Anti-Kickback Statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Because the Anti-Kickback Statute is broadly written and encompasses many harmless or efficient arrangements, Congress authorized the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, to issue a series of regulations, known as “safe harbors.” For example, there are regulatory safe harbors for payments to bona fide employees, properly reported discounts and rebates, and for certain investment interests. Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the statute. The failure of a transaction or arrangement to fit precisely within one or more of the exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that arguably implicate the Anti-Kickback Statute but do not fully satisfy all the elements of an exception or safe harbor may be subject to increased scrutiny by government enforcement authorities such as the OIG.

Many states have laws that implicate anti-kickback restrictions similar to the Anti-Kickback Statute. Some of these state prohibitions apply, regardless of whether federal health care program business is involved, to arrangements such as for self-pay or private-pay patients. Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal Civil False Claims Act and State False Claims Laws

The federal civil False Claims Act imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program, including Medicare and Medicaid. The “qui tam,” or “whistleblower” provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. Medical device companies, like us, can be held liable under false claims laws, even if they do not submit claims to the government, when they are deemed to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims.

The False Claims Act also has been used to assert liability on the basis of misrepresentations with respect to the services rendered and in connection with alleged off-label promotion of products. Our future activities relating to the manner in which we sell our products and document our prices, such as the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products, may be subject to scrutiny under these laws.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. A number of states have enacted false claim laws analogous to the federal civil False Claims Act and many of these state laws apply where a claim is submitted to any state or private third-party payer. In this environment, our engagement of physician consultants in product development and product training and education could subject us to similar scrutiny. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

HIPAA Fraud and Other Regulations

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created a class of federal crimes known as the “federal health care offenses,” including healthcare fraud and false statements relating to healthcare matters. The HIPAA health care fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, or to obtain by means of false or fraudulent pretenses, any money under the control of any health care benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment. Entities that are found to have aided or abetted in a violation of the HIPAA federal health care offenses are deemed by statute to have committed the offense and are punishable as a principal.

We are also subject to the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws applicable in non-U.S. jurisdictions that generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the U.S. will be with governmental entities and therefore subject to such anti-bribery laws.

Effective January 1, 2020, The California Consumer Privacy Act (CCPA) became effective. The CCPA provides certain privacy protections for California residents not generally available to citizens of any other state. The law provides California residents with the right to know that their personal data is being collected; know whether that data is being sold or disclosed; to prevent the sale of their personal information; to access their personal data; to request that a business delete their personal information; and to not be discriminated against for exercising these rights.

HIPAA and Other Privacy Regulations

The regulations that implement HIPAA also establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as “covered entities.” Several regulations have been promulgated under HIPAA’s regulations including: the Standards for Privacy of Individually Identifiable Health Information, or the Privacy Rule, which restricts the use and disclosure of certain individually identifiable health information; the Standards for Electronic Transactions, or the Transactions Rule, which establishes standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures; and the Security Standards for the Protection of Electronic Protected Health Information, or the Security Rule, which requires covered entities to implement and maintain certain security measures to safeguard certain electronic health information. Although we do not believe we are a covered entity and therefore are not currently directly subject to these standards, we expect that our customers generally will be covered entities and may ask us to contractually comply with certain aspects of these standards by entering into requisite business associate agreements. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards entails significant costs for us.

The Health Information Technology for Economic and Clinical Health, or HITECH, Act has increased civil penalty amounts for violations of HIPAA by either covered entities or business associates up to an annual maximum of \$1.5 million for uncorrected violations based on willful neglect. Imposition of these penalties is more likely now because HITECH significantly strengthens enforcement. It requires the Department of Health & Human Services (“HHS”) to conduct periodic audits to confirm compliance and to investigate any violation that involves willful neglect which carries mandatory penalties. Additionally, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations of HIPAA Privacy and Security Rules that threaten the privacy of state residents.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent state laws. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

Federal and state consumer protection laws are being applied increasingly by the United States Federal Trade Commission, or FTC, and state attorneys general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of web site content. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Numerous other countries have or are developing laws governing the collection, use, disclosure and transmission of personal or patient information.

HIPAA as well as other federal and state laws apply to our receipt of patient identifiable health information in connection with research and clinical trials. We collaborate with other individuals and entities in conducting research and all involved parties must comply with applicable laws. Therefore, the compliance of the physicians, hospitals or other providers or entities with whom we collaborate also impacts our business.

Third-Party Reimbursement

Our ability to market our phototherapy products successfully depends in large part on the extent to which various third parties are willing to reimburse patients or providers for the cost of medical procedures utilizing our treatment products. These third parties include government authorities, private health insurers and other organizations, such as health maintenance organizations. Third-party payers 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 payer, or is experimental, unnecessary or inappropriate. Accordingly, if less costly drugs or other treatments are available, third-party payers 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. Additionally, they may require changes to our pricing structure and revenue model before authorizing reimbursement.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. Many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems, as well as government-managed systems. Our XTRAC products remain substantially without approval for reimbursement in many international markets under either government or private reimbursement systems. To date, patients of the TheraClear products have had limited success in obtaining third party reimbursement for such treatments.

Many private plans key their reimbursement rates to rates set by the CMS under three distinct CPT codes based on the total skin surface area being treated.

As of December 31, 2023, the national rates were as follows:

- 96920 – designated for: the total area less than 250 square centimeters. CMS assigned a 2023 national payment of \$153 per treatment;
- 96921 – designated for: the total area 250 to 500 square centimeters. CMS assigned a 2023 national payment of \$168 per treatment; and
- 96922 – designated for: the total area over 500 square centimeters. CMS assigned a 2023 national payment of \$228 per treatment.

The national rates are adjusted by overhead factors applicable to each state.

Employees

As of December 31, 2023, we had 99 full-time employees, which consisted of 2 executive officers, 3 vice presidents, 35 sales and marketing staff, 28 people engaged in manufacturing of lasers, 15 customer-field service personnel, 4 engaged in research and development and 12 finance and administration staff.

Customers

Domestically, our XTRAC customers consist of dermatologists and dermatological group clinics who partner with us primarily in our dermatology procedures recurring revenue model. As of December 31, 2023, we have 923 partner clinics throughout the United States. Internationally, we have been transitioning our international dermatology procedures equipment sales through our master distributor to a direct distribution model for equipment sales and recurring revenue on a country by country basis. We have signed distributor contracts by year as follows: 2019 – Korea, 2020 – Japan, 2021 – China, Israel, Saudi Arabia, Kuwait, Oman, Qatar, Bahrain, UAE, Jordan, Iraq and 2023 – Mexico, India.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the Commission. These filings are available to the public on the Internet at the Commission's website at <http://www.sec.gov>.

Our Internet address is <http://www.strataskinsciences.com> (this website address is not intended to function as a hyperlink and the information contained on our website is not intended to be a part of this Annual Report). We make available free of charge on <https://strataskinsciencesinc.gcs-web.com/sec-filings> our annual, quarterly and current reports, and amendments to those reports, as soon as reasonably practical after we electronically file such material with, or furnish it to, the Commission. We may from time to time provide important disclosures to investors by posting them in the Investor Relations section of our website, as allowed by the Commission's rules. The information on the website listed above is not and should not be considered part of this Annual Report and is intended to be an inactive textual reference only.

ITEM 1A. RISK FACTORS

In addition to the other information contained in this Annual Report and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition, cash flows or results of operations could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business, financial condition, cash flows or results of operations. The following discussion of risk factors contains forward-looking statements as discussed on page 1. Our business routinely encounters and addresses risks, some of which may cause our future results to be different – sometimes materially different – than we presently anticipate.

Risk Factor Summary

Risks Relating to Our Business Operations

- We have incurred losses for a number of years and anticipate that we will incur continued losses for the foreseeable future.
- Public health epidemics or pandemics may affect our ability to develop, market and sell our products, disrupt regulatory activities or have other adverse effects on our business and operations.
- We may not be able to maintain an uninterrupted supply of the gases used to power our lasers, as the Russia-Ukraine War has disrupted supplies of rare gases.
- 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.
- Our laser treatments of psoriasis, vitiligo, atopic dermatitis and leukoderma and/or any of our future products or services may fail to gain market acceptance or be impacted by competitive products, services or therapies which could adversely affect our competitive position.

- 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.
- Any failure in our customer education efforts could have a material adverse effect on our revenue and cash flow.
- If revenue from significant distributors declines, we may have difficulty replacing the lost revenue, which would negatively affect our results and 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.
- We are reliant on a limited number of suppliers for production of our products.
- Our indebtedness could materially adversely affect our financial condition and our ability to operate our business, react to changes in the economy or industry or pay our debts and meet our obligations under our debt and could divert our cash flow from operations for debt payments.
- If our actual liability for state sales and use taxes is higher than our accrued liability, it could have a material impact on our financial condition.
- 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.
- 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.
- 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 failure to obtain or maintain necessary FDA clearances and approvals, or to maintain continued clearances, or equivalents thereof in the U.S. and relevant foreign markets, could hurt our ability to distribute and market our products, and our products are subject to recall by such agencies.
- If required, clinical trials necessary to support a 510(k) notice or PMA application, for new or modified products, will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.
- Healthcare policy changes may have a material adverse effect on us.
- Our market acceptance in international markets requires regulatory approvals from foreign governments and may depend on third party reimbursement of participants' cost.
- We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us.
- We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage.
- Social media companies on which we rely for advertising may change their policies limiting our ability to reach our target markets.
- 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.
- 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.
- 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.

- We may have a need for additional funds in the future and there is no guarantee that we will be able to generate those funds from our business, and if we do not have enough capital to fund operations, then we will have to cut costs or raise funds.
- 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.
- Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.

Risks Relating to Our Common Stock

- Our shares of common stock could be delisted from the Nasdaq Capital Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.
- Your percentage ownership will be further diluted.
- In the event of certain contingencies, the investors in the May 2018 Equity Financing may receive additional shares issued pursuant to the Retained Risk Provisions as defined in the purchase agreements.
- Our stock price may be volatile, meaning purchasers of our common stock could incur substantial losses.
- Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of our stock.

Risks Relating to Our Business Operations

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

Since 2015, we have devoted substantially all of our resources in the commercialization and sales of the XTRAC products. Our net loss for the year ended December 31, 2023 was approximately \$10.8 million, and as of December 31, 2023, we had an accumulated deficit of approximately \$238.1 million. Our losses, among other things, have had and may continue to have an adverse effect on the adequacy of our capitalization and cash flow.

Public health epidemics or pandemics may affect our ability to develop, market and sell our products, disrupt regulatory activities or have other adverse effects on our business and operations. In addition, public health epidemics or pandemics may adversely impact economies worldwide, which could result in adverse effects on our business, operations and prospects.

Our business and operations could be adversely affected by public health epidemics or pandemics, including the recent COVID-19 pandemic, impacting the markets and industries in which we and our collaborators operate. We and our partners have faced and may in the future face disruptions that affect our ability to operate due to various factors, including:

- the ability to source raw materials and supplies;
- a general decline in business activity;
- the destabilization of the markets and negative impacts on the healthcare system globally, which could negatively impact our ability to market and sell our products, including through the disruption of health care activities in general and elective health care procedures in particular, the inability of our sales team to contact and/or visit doctors in person, patients' interest in starting or continuing procedures involving our products and our ability to support patients that presently use our products; and
- difficulty accessing the capital and credit markets on favorable terms, or at all, and a severe disruption and instability in the global financial markets, or deteriorations in credit and financing conditions which could affect our access to capital necessary to fund business operations.

Further, the Biden Administration ended the public health emergency declarations related to the COVID-19 pandemic in May 2023 and the FDA ended a number of COVID-related policies. The FDA has retained a number of COVID-19-related policies but with appropriate changes, as applicable. It is unclear how, if at all, these policies will impact our efforts to develop and commercialize our products.

We may in the future face impediments or delays to regulatory meetings and approvals due to any pandemic measures. We cannot be certain what the overall impact of such pandemics will be on our business, although for the reasons described above such pandemics have the potential to adversely affect our business, financial condition, results of operations and prospects.

We may not be able to maintain an uninterrupted supply of the gases used to power our lasers, as the Russia-Ukraine War has disrupted supplies of rare gases.

Prior to the outbreak of the Russia-Ukraine War, Ukraine was the world's largest exporter of noble gases including neon, krypton and xenon. Historically, Ukraine has been the source of a significant amount of gas supplied to the Company by our contract suppliers. Neon gas is essential to the proper functioning of our lasers. Our suppliers have been resourceful in continuing to supply gases to us but cannot assure us that the supply will remain uninterrupted. The reduced supply and war have also impacted the price of gas worldwide. Additionally, the Creating Helpful Incentives to Produce Semiconductors and Science Act of 2022 has led to a further tightening of rare gas supplies as chip manufacturers reconfigure their supply chains to address the need to secure their own supplies of rare gases for use in the manufacture of computer chips, while struggling with the disruption caused by this war.

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, and such 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 (including the Pharos and TheraClear businesses), 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; and
- 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 and could increase losses and losses per share which could impact the price of our stock.

Our laser treatments of psoriasis, vitiligo, atopic dermatitis and leukoderma and/or any of our future products or services may fail to gain market acceptance or be impacted by competitive products, services or therapies 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 placed at physician offices at no upfront charge to the physician and we are generally paid on a per-usage method where we retain ownership of the system. We cannot assure you that our products and services will find sufficient acceptance in the marketplace under our sales strategies.

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 financial return and therefore compromise our ability to increase our installed base of users and ensure they engage in optimal usage of our products. If, for example, such other companies have products or medical devices 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.

We also face a risk that the overall cost of systemic or biologic medications or treatment modalities become less expensive through the development of generics or other means. We may be faced with pressure to reduce our costs to be competitive which may negatively impact our business. In addition, our business could be negatively impacted if these medications are prescribed for less severe cases of the diseases or if new, more effective or less expensive medications are developed.

Whether a treatment may be delegated to non-physician staff members 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, deeming it to be fraught with too many constraints and finding other outlets for the physician's time and staff's 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. Failure of our products to achieve market acceptance could have a material adverse effect on our business, financial condition and results of operations.

In addition, while this introduction is specifically for those patients that might not be able to avail themselves of in-office treatments, it may be viewed by our partner clinics as a channel conflict and cause a deterioration in our relationships with our current partners or negatively impact our ability to grow the number of partner clinics.

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 ACA.

Third-party payers 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 payer, 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 payers 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 current or any 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.

CPT codes for all procedures are subject to continued reevaluation. Should CMS reduce reimbursement for the CPT codes for XTRAC treatment or raise reimbursement for competitive products, we may see a decline in our recurring revenue business as well as a decline in new XTRAC installations.

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 payers may require further clinical studies or changes to our pricing structure and revenue model before authorizing or continuing reimbursement.

As of December 31, 2023, based on published coverage policies and payment practices of private and Medicare insurance plans, we estimate that more than 86% 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.

Currently, there is little insurance reimbursement coverage for acne treatments, such as those provided by TheraClear. In order for TheraClear to be successful, patients and decision makers will need to be able to pay for treatments without insurance reimbursement.

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

The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the U.S. Department of Justice, or DOJ for improper relationships with physicians. Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations.

Any failure in our customer education efforts could have a material adverse effect on our revenue and cash flow.

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 profitability.

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

We depend on several key distributors for a material portion of our sales, especially in our international business. While we no longer rely upon a single master distributor for our international sales, we now rely upon several in-country distributors in connection with this business. If, for example, a distributor finds that the financial incentives underlying the distributor relationship are no longer attractive, we may need to reduce our margins in order to continue the relationship or identify a new distributor, which could take a significant amount of time. This could have a significant negative effect on our results and our operations, including, but not limited to, failing to comply with a financial covenant in our credit facility with MidCap.

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 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 treatments 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 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 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, premarketing authorization and Quality System Requirements (“QSR”).

Our indebtedness could materially adversely affect our financial condition and our ability to operate our business, react to changes in the economy or industry or pay our debts and meet our obligations and could divert our cash flow from operations for debt payments.

In September 2021, we entered into a secured borrowing facility with MidCap Financial Trust (“MidCap”), which was amended in January 2022, September 2022 and June 2023 (the “Senior Credit Facility”). On February 20, 2024, we amended the Senior Credit Facility to, among other things, revise the applicable minimum net revenue threshold financial covenant (the “Amendment”). Because we were not in compliance with the applicable minimum net revenue financial threshold covenant for the period ended December 31, 2023, MidCap and the lenders in the Amendment agreed to, among other things, grant a limited waiver of the foregoing event that had occurred prior to the effectiveness of the Amendment and of any right the lenders may have to exercise any of their rights against us as a result. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources” for discussion included in Item 7 of this Annual Report on Form 10-K. In addition, subject to restrictions in the agreements governing our credit facilities, we may incur additional debt.

Our indebtedness could have negative consequences, including the following:

- it may be difficult for us to satisfy our obligations, including debt service requirements under our outstanding debt, resulting in possible defaults on and acceleration of such indebtedness;
- our ability to obtain additional financing for working capital, capital expenditures, debt service requirements, acquisitions or other general corporate purposes may be impaired;
- a substantial portion of cash flow from operations may be dedicated to the payment of principal and interest on our debt, therefore reducing our ability to use our cash flow to fund our operations, capital expenditures, future business opportunities, acquisitions and other purposes;
- we are more vulnerable to economic downturns and adverse industry conditions and our flexibility to plan for, or react to, changes in our business or industry is more limited;
- our ability to capitalize on business opportunities and to react to competitive pressures, as compared to our competitors, may be compromised due to our high level of debt; and
- our ability to borrow additional funds or to refinance debt may be limited.

Furthermore, all of our debt under the Senior Credit Facility bears interest at variable rates. As these rates increase as they did in 2023, our debt service obligations increase even though the amount borrowed remains the same, and our net income and cash flows, including cash available for servicing our indebtedness, correspondingly decrease. If interest rates continue to increase, we will see a corresponding increase in these obligations. Accordingly, our ability to borrow additional funds may be reduced and risks related to our indebtedness would intensify. Each quarter-point increase in the variable interest rates would increase interest expense on our current variable rate debt by approximately \$38,000 during 2024.

The Financial Conduct Authority (the authority that regulates the London Interbank Offer Rate (“LIBOR”)) announced it intended to stop compelling banks to submit rates for the calculation of LIBOR after June 30, 2022. We transitioned to the one month Secured Overnight Financing Rate (“SOFR”) in connection with the amended Senior Credit Facility. SOFR is a daily index of the interest rate banks and hedge funds pay to borrow money overnight, secured by U.S. Treasury securities. We also anticipate that we may use SOFR as the interest rate index in future agreements. SOFR differs fundamentally from LIBOR. For example, SOFR is a secured overnight rate, while LIBOR is an unsecured rate that represents interbank funding over different maturities. In addition, because SOFR is a transaction-based rate, it is backward-looking, whereas LIBOR is forward-looking. Because of these and other differences, there can be no assurance that SOFR will perform in the same way as LIBOR would have done at any time, and there is no guarantee that it is a comparable substitute for LIBOR.

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

Included in accrued state sales and use taxes are certain known and estimated sales and use taxes and related penalties and interest to taxing authorities. In our recurring revenue model, we place the XTRAC system in the physician’s office under an arrangement for no upfront charge and generate our revenue on a per-use basis.

In the ordinary course of business, we are, from time to time, subject to audits performed by state taxing authorities. These actions and proceedings are generally based on the state’s position that the arrangements entered into by the Company are subject to state sales and use tax rather than exempt from applicable law. We are currently under audit by two taxing jurisdictions as it pertains to state sales and/or use tax. The State of New York has assessed us, in three assessments, an aggregate amount of \$2.7 million including penalties and interest. The audits cover the period from March 2014 through November 2022. In January 2021, we received notification that the administrative judge in this jurisdiction had issued an opinion finding in favor of us that the sale of XTRAC treatment codes were not taxable as sales tax with respect to the first assessment, which amounted to \$1.4 million. The relevant taxing authority filed an appeal of the administrative law judge’s finding and, following the submission of legal briefs by both sides and an oral argument held in January 2022, on May 6, 2022, we received a written decision from the State of New York Appeals Tribunal (“Tribunal”) overturning the favorable sales tax determination of the administrative law judge. We appealed the Tribunal’s decision to the New York State Appellate Division (“Appellate Division”), and posted the required appellate bond in the form of cash collateral. Oral argument was held by the Appellate Division on January 18, 2024. We are in the administrative process of appeal with respect to the remaining \$1.3 million of assessments in the State of New York.

On March 8, 2024, we received a decision from the Appellate Division ruling against us in the matter of our sales tax appeal, affirming the Tribunal’s ruling that our sale of XTRAC treatment codes is subject to sales tax. The Appellate Division concluded that, through the usage arrangements, our customers had possession of the laser devices and had a license and ability to use the laser devices. The Appellate Division also agreed with the Tribunal that the primary function analysis was not applicable in this matter. We will be filing a motion to appeal the Appellate Division’s decision.

The State of California has made aggregate assessments of \$1.2 million including penalties and interest. The audits cover the period from June 2018 through June 2022. We are in the administrative appeal process in this jurisdiction as well. In the event there is a determination that the true object of the delivery of phototherapy under the recurring revenue model is a sale or lease of property and it is not a prescription medication, or we do not have other defenses where we prevail, we may be subject to state sales taxes in those particular states for previous years and in the future, plus interest and penalties for failure to pay such taxes. If it was determined that our recurring revenue model was not exempt from sales taxes in all states where we do business, and taxes and penalties were imposed in each of those states for the entire period through the expiration of each state’s statute of limitations, state sales and use tax, penalties and interest for such period would have a material negative impact on our financial condition and cash flow.

As of December 31, 2023 and 2022, we have estimated our sales and use tax liability to be approximately \$4.3 million and \$4.0 million, respectively. We believe our sales and use tax accruals have properly recognized that if our arrangements with customers are deemed more likely than not that we would not be exempt from sales tax in a particular state are the basis for measurement of the state sales and use tax is calculated in accordance with ASC 405, *Liabilities*, as a transaction tax. While we believe we have strong positions that our recurring revenue is exempt from sales tax, if it is found that we are subject to sales tax in those particular states where we believe it is more likely than not that we would be exempt from sales tax, then potential tax liabilities including interest and penalties would be higher than accrued amounts. The precise scope, timing and time period at issue, as well as the final outcome of any audit and actual settlements, remain uncertain.

Our failure to respond to rapid changes in technology and other 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.

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

We presently maintain liability insurance with coverage limits of at least \$5.0 million per occurrence and overall aggregate, which we believe is an adequate level of product liability insurance, 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. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. 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. Even successful defense would require significant financial and management resources. 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, harm to our reputation, withdrawal of clinical trial volunteers, initiation of investigations by regulators, costs to defend the related litigation, diversion of management's time and our resources, monetary awards to trial participants or patients, product recalls, withdrawals or labeling, marketing or promotional restrictions, exhaustion of any available insurance and our capital resources, a resulting decline in the price of our common stock 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 HHS 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, and 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.

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 payers, 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 laws, 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 payers 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;
- 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 payer, 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 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 premarket 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 and approvals, or to maintain continued clearances, 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 our 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 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 12 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 11 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 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.

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

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

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Effective January 2022 we are also required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations.

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

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, for new or modified products, 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.

Initiating and completing clinical trials necessary to support a 510(k) notice or a PMA application 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 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 payers, 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, payers, 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. They imposed on medical device manufacturers, a requirement to research into the effectiveness of treatment modalities and institute 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. Furthermore, 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 loss from continuing operations 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. Our TheraClear device has historically been sold in several foreign countries and is subject to similar international regulatory approval requirements.

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

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

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

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Competition for these people in the medical device industry is intense and we may face challenges in retaining and recruiting such individuals if, for example, other companies may provide more generous compensation and benefits, more diverse opportunities, and better chances for career advancement than we do. Some of these advantages may be more appealing to high-quality candidates and employees than those we have to offer. In addition, the decline in our stock price has created additional challenges by reducing the retention value of our equity awards. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology, which would have a material adverse effect on our business, financial condition, and results of operations.

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

Many medical device industry companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to bundle the sale of more products to our customers in return for lower prices. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease and our earnings, financial condition, or cash flows would suffer, which would have a material adverse effect on our business, financial condition, and results of operations.

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

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

Social media companies on which we rely for advertising may change their policies limiting our ability to reach our target markets.

We rely on social media companies, such as Facebook and Twitter, to reach our target markets. Facebook has announced that beginning in January 2022 it will limit the ability of advertisers to target certain markets. Any restrictions by Facebook or any other social media platform on which we depend to reach our target market could have a significant impact on our ability to develop customer awareness and generate new users for our physician partners.

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. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing our products, and/or could enter an order mandating that we undertake certain remedial activities. 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.

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 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 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 have a need for additional funds in the future and there is no guarantee that we will be able to generate those funds from our business.

Our existing cash position and ability to borrow funds and future revenue may not be sufficient to support the expenses of our operations in the near term. We plan to fund operations by the recurring revenue generated by the use of the XTRAC lasers and the TheraClear Acne Therapy System in the U.S. and international markets, as well as domestic and international sales of our products. If revenues from the sale and use of our existing products are inadequate to fund our operations, we may need to raise additional financing. We cannot assure you that we will be able to raise additional capital or secure alternate financing to fund operations, if necessary, or that we will be able to raise additional capital under terms that are favorable to us. Further, we cannot assure that an acquisition will in any way negate or mitigate our need for future capital. Any additional financing may dilute the ownership interest of our existing stockholders and could adversely affect the market price of our common stock.

If we do not have enough capital to fund operations, then we will have to cut costs or raise funds.

If we are unable to raise additional funds, if necessary, under terms acceptable to us and in the interests of our stockholders, then we will have to take measures to cut operating costs or obtain funds using alternative methods, such as:

- Sell or license some of our technologies that we would not otherwise sell or license if we were in a stronger financial position;
- Sell or license some of our technologies under terms that are less favorable than they otherwise might have been if we were in a stronger financial position; and
- Consider further business combination transactions with other companies or positioning ourselves to be acquired by another company.

If it became necessary to take one or more of the above-listed actions, then our perceived valuation may be lower, which could impact the market price of our stock. Further, the effects on our operations, financial performance and stock price may be significant if we do not or cannot take one or more of the above-listed actions in a timely manner and when needed, and our ability to do so may be limited significantly due to the instability of the global financial markets and the resulting limitations on available financing to us and to potential licensees, buyers and investors. Additionally, these options may not be available to us as all of our assets have been pledged as security for the various financings.

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 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.

While we have implemented a number of protective measures, including firewalls, antivirus, patches, data encryption, log monitors, routine backups 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.

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

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

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Israel and Hamas, the ongoing war between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the sanctions relating to Russia, may also adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Risks Relating to Our Common Stock

Our shares of common stock could be delisted from the Nasdaq Capital Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.

Our common stock is currently listed on the Nasdaq Capital Market. To maintain the listing of our common stock on the Nasdaq Capital Market, we are required to meet certain listing requirements, including, among others, (i) a minimum closing bid price of \$1.00 per share, (ii) a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and (iii) either: (x) stockholders' equity of at least \$2.5 million; or (y) a total market value of listed securities of at least \$35 million.

On June 29, 2023, we received a notification from the Listing Department of Nasdaq indicating that during the preceding 30 consecutive business day period, the closing price of our common stock was below \$1.00 per share. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until December 26, 2023, to regain compliance. To regain compliance, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of ten consecutive business days. In order to regain compliance, we proposed, and, on October 26, 2023, our stockholders approved, a proposal to effect a reverse stock split of our common stock at a ratio of not less than 1 for 5 and no greater than 1 for 25, with the exact ratio, if effected at all, to be set within that range approved at the discretion of our board of directors and publicly announced by April 26, 2024 without further approval or authorization of our stockholders. On December 27, 2023, we received written notice from Nasdaq that we have been granted a 180-day extension, or until June 24, 2024, to regain compliance with Nasdaq's minimum bid price rule.

Even if a reverse stock split is effected, there can be no assurance that the market price per share of our common stock will remain in excess of the \$1.00 minimum bid price for a sustained period of time. The continuing effect of a reverse stock split on the market price of our common stock cannot be predicted with any certainty, and the history of similar stock split combinations for companies in like circumstances is varied. It is possible that the per share price of our common stock after a reverse stock split will not rise in proportion to the reduction in the number of shares of common stock outstanding resulting from a reverse stock split, effectively reducing our market capitalization, and there can be no assurance that the market price per post-reverse split share will either exceed or remain in excess of the \$1.00 minimum bid price for a sustained period of time. The market price of our common stock may vary based on other factors that are unrelated to the number of shares outstanding, including our future performance.

If we do not meet the minimum stockholders' equity, minimum closing bid price requirements, or any other listing requirements, we would be subject to delisting from the Nasdaq Capital Market. The delisting of our common stock from a national exchange could impair the liquidity and market price of the common stock. It could also materially, adversely affect our access to the capital markets, and any limitation on market liquidity or reduction in the price of the common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

Your percentage ownership will be further diluted in the future.

Your percentage ownership in our common stock will be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees. Our Equity Incentive Plan provides for the grant of equity-based awards, including restricted stock, restricted stock units, stock options, stock appreciation rights and other equity-based awards to our directors, officers and other employees, advisors and consultants. In connection with the Senior Credit Facility, as amended, we issued a warrant to MidCap Financial Trust to purchase 800,000 shares of our common stock, with an exercise price of \$0.88 per share. We also maintain a shelf-registration statement that provides us with the ability, from time to time, to offer and sell up to \$25.0 million in securities, including selling up to \$11.0 million of our common stock in registered "at-the-market" offerings pursuant to an equity distribution agreement entered into with Ladenburg Thalmann & Co. Inc. in October 2021. As a result of shares sold or issued under the circumstances described above, your percentage ownership in our common stock will be diluted in the future.

In the event of certain contingencies, the investors in the May 2018 Equity Financing may receive additional shares issued pursuant to the Retained Risk Provisions as defined in the purchase agreements.

In the event of certain contingencies, the investors in the May 2018 equity financing may receive additional shares issued pursuant to the Retained Risk Provisions as defined in the Stock Purchase Agreements. At the closing, the Company determined certain contingencies had been met and, in July 2018, the Company issued 153,004 shares associated with those contingencies. There were additional contingencies included in the SPAs that expired in May 2020 and did not result in the issuance of shares.

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 and any perceived need to raise additional funds;
- variations in our financial results from expected 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. In connection with the financing in May 2018, our board of directors exempted AGP SPVI, L.P. from the application of this provision in connection with its investment.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Our Board of Directors administers its cybersecurity risk oversight function directly through our Audit Committee (the "Committee"). The Committee has primary responsibility for overseeing our risk management practices, programs, policies, and procedures related to data privacy, data protection, and cybersecurity. The Committee reviews and evaluates the processes utilized by management to identify and assess the material internal and external risks that may affect our business. The Committee regularly discusses with management, legal counsel, and the internal audit department our major risk exposures. This includes potential financial impact on us and the steps taken to monitor and control those risks. Reviews with management are done annually, which includes a summary of legal and regulatory compliance matters and risk management activities, and a review of our cybersecurity program. Additionally, the Committee oversees the process by which our Board of Directors is informed regarding the risks facing us and coordinates with our legal counsel to ensure our Board of Directors receives regular risk assessment updates from management.

Our IT Manager has been designated as our Chief Information Security Officer ("CISO"), who is responsible for identifying, assessing and managing our risks from cybersecurity threats. The CISO has been with the Company for over five years and has many years of experience in technology. The CISO is supported by our outside IT consulting firm and its cybersecurity team that is staffed with personnel experienced in cyber security, security operations and incident management.

The CISO reports to the CFO, who provides the Committee with bi-annual updates about our cybersecurity program and material risks.

Risk Management and Strategy

Processes for identifying and assessing cybersecurity risks

The CISO, with the support of the outside consultant's cybersecurity team and the owners of information technology across the business, monitors current events and trends related to cybersecurity and assesses any potential impact on current systems and operations. There are several processes in place to monitor and review our systems, including third-party solutions, to identify potential risks. Third-party service providers are required to notify us in the event of a cybersecurity incident within their systems, and annual reviews are conducted on our critical third-party vendors. Cybersecurity risks, threats, and incidents, including those from third-party service providers, are tracked and regularly provided to the CISO.

Processes for managing cybersecurity risks

The cybersecurity team tracks risks and incidents related to cybersecurity until the risk is mitigated to an acceptable level or fully remediated. When risks are identified, the cybersecurity team oversees mitigation plans with the risk owner which are communicated to necessary teams and remediation steps are taken.

Processes for incorporating cybersecurity risks into the overall risk management process

Our process for identifying, assessing, and managing risks related to cybersecurity is incorporated into our IT processes. The Risk Management team meets at least annually with cybersecurity leadership to discuss cybersecurity related risks identified and the potential likelihood and severity of each risk. Through this process, cybersecurity risks are presented to the executive leadership team, including the CEO and CFO, as well as reported to the Committee.

Currently, we are not aware of any risks from cybersecurity threats, or from previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect the Company.

ITEM 2. PROPERTIES

We lease an 8,513 sq. ft. facility in Horsham, Pennsylvania that houses our executive offices and marketing. The lease was set to expire in January 2023. In August 2022, we exercised the lease renewal option and extended the term of the lease to expire in August 2026.

We lease a 17,000 sq. ft. facility consisting of office, manufacturing and warehousing space in Carlsbad, California. On May 1, 2019, we entered into the Fifth Amendment to the lease. The term of the lease commenced on October 1, 2019 and expires on September 30, 2024. Our Carlsbad facility houses the manufacturing and development operations for our excimer laser business, as well as the patient call center and reimbursement center.

ITEM 3. LEGAL PROCEEDINGS

From time to time in the ordinary course of our business, we may be a party to certain legal proceedings, incidental to the normal course of our business. These may include controversies relating to contract claims and employment related matters, some of which claims may be material, in which case, we will make separate disclosure as required.

On April 1, 2022, a proposed representative class action under California's Private Attorneys General Act ("PAGA") was filed in Superior Court of California, County of San Diego against the Company and an employment agency ("Co-Defendant") which provided us with temporary employees. The complaint alleges various violations of the California Labor Code, including California's wage and hour laws, relating to certain of our current and former non-exempt employees. The complaint seeks class status and payments for allegedly unpaid compensation and attorney's fees. In a related matter, the attorneys in this matter and the proposed class representative, in a letter dated March 12, 2022, to the California Labor & Workforce Development Agency made nearly identical claims seeking the right to pursue a PAGA action against us and the employment agency. On or about May 16, 2022, the plaintiff filed a First Amended Complaint adding a PAGA claim to the action. On or about June 2, 2022, the plaintiff filed an Application to Dismiss Class and Individual Claim without prejudice, in an attempt to pursue a PAGA only complaint. On or about June 30, 2022, the parties entered into a stipulation to allow the plaintiff to file a Second Amended Complaint to clarify the PAGA claim and to stay the pending action to allow mediation. The mediation was held on February 23, 2023, and the matter was settled on terms agreeable to us. The settlement, which requires us to pay \$0.1 million, was subject to the right of individual class members to reject the settlement and proceed on their own. No individual has requested to opt out of the settlement.

In the ordinary course of business, we are, from time to time, subject to audits performed by state taxing authorities. These actions and proceedings are generally based on the position that the arrangements entered into by us are subject to sales and use tax rather than exempt from tax under applicable law. The states of New York and California have assessed us an aggregate of \$3.9 million including penalties and interest. The audits cover the period from March 2014 through November 2022. We received notification that an administrative state judge in New York issued an opinion finding in favor of us that the sale of XTRAC treatment codes was not taxable as sales tax with respect to that state's first assessment. This ruling covers \$1.4 million of the total \$3.9 million of assessments. The relevant taxing authority filed an appeal of the administrative law judge's finding and, following the submission of legal briefs by both sides and oral argument held in January 2022, on May 6, 2022, we received a written decision from the State of New York Appeals Tribunal ("Tribunal") overturning the favorable sales tax determination of the administrative law judge. We appealed the Tribunal's decision to the New York State Appellate Division ("Appellate Division"), and posted the required appellate bond in the form of cash collateral. Oral argument was held by the Appellate Division on January 18, 2024.

On March 8, 2024, we received a decision from the Appellate Division ruling against us in the matter of our sales tax appeal, affirming the Tribunal's ruling that our sale of XTRAC treatment codes is subject to sales tax. The Appellate Division concluded that, through the usage arrangements, our customers had possession of the laser devices and had a license and ability to use the laser devices. The Appellate Division also agreed with the Tribunal that the primary function analysis was not applicable in this matter. We will be filing a motion to appeal the Appellate Division's decision.

We are also in the administrative process of appeal with respect to the remaining \$2.5 million of assessments. If there is a determination that the true object of our recurring revenue model is not exempt from sales taxes and is not a prescription medicine, or we do not have other defenses where we prevail, we may be subject to sales taxes in those particular states for previous years and in the future, plus potential interest and penalties.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II**ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

As of March 20, 2024, we had 35,060,920 shares of common stock issued and outstanding, which are listed on the Nasdaq Capital Markets under the symbol “SSKN.” This did not include (i) options to purchase 5,391,069 shares of common stock, of which 1,146,465 were vested as of March 20, 2024, (ii) unissued restricted stock units of 22,654, or (iii) 800,000 shares of common stock reserved for issuance pursuant to a warrant.

DIVIDEND POLICY

We have not declared or paid any dividend on our common stock, since our inception. We do not anticipate that any dividends on our common stock will be declared or paid in the future. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on then existing conditions, including our earnings, financial condition, results of operations, level of indebtedness, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our board of directors’ ability to declare a dividend is also subject to limits imposed by Delaware law and our credit facility.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

Equity Compensation Plan Information

The following is a summary of all of our equity compensation plans, including plans that were assumed through acquisitions and individual arrangements that provide for the issuance of equity securities as compensation, as of December 31, 2023. See Notes 1 and 13 to the consolidated financial statements for additional discussion.

Plan Category	Number of securities to be issued upon exercise of outstanding securities (#)	Weighted average exercise price of outstanding options (\$)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (#)
	(a)	(b)	(c)
Equity compensation plans approved by security holders	7,728,721	\$ 1.11	1,329,375
Equity compensation plans not approved by security holders	—	—	—
	<u>7,728,721</u>	<u>\$ 1.11</u>	<u>1,329,375</u>

RECENT SALES OF UNREGISTERED SECURITIES; USE OF PROCEEDS FROM REGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our consolidated financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties as described under the heading "Cautionary Note Regarding Forward-Looking Statements" elsewhere in this Annual Report. You should review the disclosure under the heading "Risk Factors" in this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

STRATA Skin Sciences, Inc. is a medical technology company in dermatology dedicated to developing, commercializing, and marketing innovative products for the treatment of dermatologic conditions. Its products include the XTRAC® and Pharos® excimer lasers and VTRAC® lamp systems utilized in the treatment of psoriasis, vitiligo, and various other skin conditions, as well as the TheraClear® X Acne Therapy System utilized in the treatment of acne-related skin conditions.

The XTRAC ultraviolet light excimer laser system is utilized to treat psoriasis, vitiligo, and other skin diseases. The XTRAC excimer laser system received clearance from the United States Food and Drug Administration 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 December 31, 2023, there were 923 XTRAC systems placed in dermatologists' offices in the United States under our dermatology recurring procedures model, an increase from 909 as of December 31, 2022. Under the dermatology recurring procedures 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, provides targeted therapeutic efficacy demonstrated by excimer technology with the simplicity of design and reliability of a lamp system. The Pharos excimer laser system holds FDA clearance to treat chronic skin diseases, including psoriasis, vitiligo, atopic dermatitis, and leukoderma. We believe there are approximately 8 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.

The TheraClear® X Acne Therapy System combines intense pulse light with vacuum (suction) for the treatment of mild to moderate inflammatory acne (including acne vulgaris), comedonal acne and pustular acne. The TheraClear device was cleared by the FDA through the 510(k) process. Currently, there is little insurance reimbursement coverage for acne treatments, such as those provided by TheraClear.

Our non-U.S. business focuses on a direct distribution model for equipment sales and recurring revenue, and we have distribution agreements in place in the Mid-East, Asia, and Mexico.

Post-COVID-19 Pandemic

In late 2019, there was an outbreak of a new strain of coronavirus (“COVID-19”) which became a global pandemic. Since March 2020, the COVID-19 pandemic has negatively impacted business conditions in the industry in which we operate, disrupted global supply chains, constrained workforce participation, and created significant volatility and disruption of financial markets. The pandemic led to the suspension of elective procedures in the U.S. and to the temporary closure of many physician practices, which are our primary customers. While most offices have reopened, some physician practices closed and never reopened, and the impact of the COVID-19 pandemic and its variants on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frames, will depend on future developments, including, but not limited to, impact on supply chains and transport, and governmental and customer responses, including staffing issues, all of which are uncertain and cannot be predicted. While the COVID-19 pandemic has largely subsided, we are unable to fully evaluate the long-term effects of changes to customer behavior and our supply chain network. We will continue to identify and plan around potential future pandemics and disruptions to our business.

Impact of Russia-Ukraine War

Prior to the outbreak of the Russia-Ukraine War, Ukraine was the largest exporter of noble gases including neon, krypton, and xenon and has historically been the source of a significant amount of gas supplied to us by our contract suppliers. Neon gas is essential to the proper functioning of our lasers. Our suppliers have been resourceful in continuing to supply gases to us but cannot assure us that the supply will not remain uninterrupted. The reduced supply and ongoing conflict have also impacted the price of gas worldwide. Additionally, the Creating Helpful Incentives to Produce Semiconductors and Science Act of 2022 has led to a further tightening of rare gas supplies as semiconductor chip manufacturers reconfigure their supply chains to address the need to secure their own supplies of rare gases for use in the manufacture of computer chips.

Key Technologies

- *XTRAC® Excimer Laser.* XTRAC received FDA clearance in 2000 and has since become a widely recognized treatment among dermatologists for psoriasis and other skin diseases. The XTRAC System delivers ultra-narrowband ultraviolet B (“UVB”) light to affected areas of skin. Following a series of treatments typically performed twice weekly, psoriasis remission can be achieved, and vitiligo patches can be re-pigmented. XTRAC is endorsed by the National Psoriasis Foundation, and its use for psoriasis is covered by nearly all major insurance companies, including Medicare. We estimate that more than half of all major insurance companies now offer reimbursement for vitiligo as well, a figure that is increasing.
- In the third quarter of 2018, we announced the FDA granted clearance for our Multi Micro Dose (MMD) tip for our XTRAC excimer laser. The MMD Tip accessory is indicated for use in conjunction with the XTRAC laser system to filter the Narrow Band UVB (“NB-UVB”) light at delivery in order to calculate and individualize the maximum non-blistering dose for a particular patient.
- In January 2020, we announced the FDA granted clearance of our XTRAC Momentum Excimer Laser Platform. In February 2022, we announced the commercial launch, with the first installation in the U.S. market, of our next generation excimer laser system, XTRAC Momentum® 1.0.
- *VTRAC® Lamp.* VTRAC received FDA clearance in 2005 and provides targeted therapeutic efficacy demonstrated by excimer technology with the simplicity of design and reliability of a lamp system.
- *TheraClear® X Acne Treatment Device.* The TheraClear® Acne Therapy System combines intense pulse light with vacuum (suction) for the treatment of mild to moderate inflammatory acne (including acne vulgaris), comedonal acne and pustular acne.

Recent Developments

TheraClear Acquisition

In January 2022, we acquired certain assets related to the TheraClear devices from Theravant Corporation (“Theravant”). The TheraClear asset acquisition will allow us to further develop, commercialize and market the TheraClear devices that are used for acne treatment, as well as advance the TheraClear technology into multiple other devices that can be used to treat a range of additional indications.

We made an upfront cash payment of \$0.5 million and issued to Theravant 358,367 shares of common stock with an aggregate value of \$0.5 million in connection with the TheraClear asset acquisition. During the fourth quarter of 2022, we also made a \$0.5 million milestone payment upon the launch of the TheraClear Acne Therapy System, one of the development-related targets. Theravant is eligible to receive up to \$3.0 million in future earnout payments upon achievement of certain annual net revenue milestones, up to \$20.0 million in future royalty payments based upon a percentage of gross profit from future domestic sales ranging from 10-20%, 25% of gross profit from international sales over the subsequent four-year period, and up to \$0.5 million in future milestone payments upon the achievement of certain commercialization related targets.

We officially launched our TheraClear® X Acne Therapy System in January 2023. Through December 31, 2023, we have incurred \$0.1 million of royalty and gross profit payments based on gross profit from domestic and international sales.

MidCap Financing

On June 30, 2023, we completed the refinancing of our existing debt agreement with a new facility from MidCap Financial Trust (“MidCap”). The new debt facility consists of a refinancing of the existing \$8.0 million term loan and an additional \$7.0 million tranche funded at closing. We also have the option to receive an additional \$5.0 million tranche in 2024. The debt agreement was further amended on February 20, 2024 to, among other things, revise the applicable minimum net revenue threshold financial covenant. (For more information, see Notes 1, **Organization and Nature of Business** and 10, **Long-term Debt** to the Notes to Consolidated Financial Statements.)

Reverse Stock Split

On June 26, 2023 we were notified by Nasdaq that we were not in compliance with Nasdaq’s minimum closing bid price listing standard. We have until June 24, 2024 to regain compliance with this rule. As a result, on October 26, 2023, our stockholders approved a proposal authorizing a reverse stock split of our common stock at a ratio of not less than 1 for 5 and no greater than 1 for 25, with the exact ratio, if effected at all, to be set within that range approved at the discretion of our board of directors and publicly announced by April 26, 2024 without further approval or authorization of our stockholders.

Management Agreements

On October 26, 2023, the board of directors authorized the execution of two agreements related to a change in management of the Company and the execution of a third agreement related to compensation of an executive officer.

The three agreements are as follows:

- Effective October 30, 2023, (a) Robert Moccia stepped down as our President and Chief Executive Officer and as a member of our board of directors; and (b) the Company and Christopher Lesovitz, our Chief Financial Officer, entered into a retention agreement, pursuant to which, in accordance with the terms and conditions of such agreement, Mr. Lesovitz will receive an aggregate cash bonus equal to \$0.1 million.
- On October 31, 2023, Dr. Dolev Rafaeli was appointed as our Vice-Chairman, President and Chief Executive Officer and as a member of our board of directors. In connection with such appointment, on October 31, 2023, we issued Dr. Rafaeli an option to purchase 1,745,569 shares of common stock, with a strike price of \$0.53 per share, vesting over a three-year period.

Components of Results of Operations

Revenues

To date, we have generated revenues primarily from the placement of our lasers in physicians' offices and the related sales and rentals and the recurring revenues from our sale of treatment sessions.

Dermatology Recurring Procedures Segment: we have primarily two types of arrangements for our phototherapy treatment equipment as follows: (i) we place our lasers in a physician's office at no charge to the physician, and generally charge the physician a fee for an agreed upon number of treatments; or (ii) we place our lasers in a physician's office and charge the physician a fixed fee for a specified period of time not to exceed an agreed upon number of treatments; if that number is exceeded additional fees will be paid.

Dermatology Procedures Equipment Segment: we sell our products internationally through distributors and domestically, directly to a physician. We also derive revenues from service and repair extended warranty contracts with our existing customers.

We refer you to the section titled "—Critical Accounting Policies and Use of Estimates—Revenue Recognition" appearing elsewhere in this Annual Report for additional information regarding how we account for revenues.

Sales in the United States represented 69% and 66% of our total revenues for the years ended December 31, 2023 and 2022, respectively, and have been generated by our direct sales force. Outside the United States, our sales are made through third-party distributors. International revenues were 31% and 34% for the years ended December 31, 2023 and 2022, respectively. We expect that both our United States and international revenues will increase in the near term as we continue to expand our product offerings and increase the related patient utilization in the United States, as well as grow our presence in Asia.

Cost of Revenues and Gross Margin

Cost of revenues primarily consists of the costs of components and the manufacture of our XTRAC and VTRAC systems. Cost of revenues also includes costs related to personnel, depreciation, amortization, warranty, shipping, and our operations and field service departments.

Our gross profit is calculated by subtracting our cost of revenues from our revenues. We calculate our gross margin as our gross profit divided by our revenues. Our gross margin has been and will continue to be affected by a variety of factors, primarily product sales mix and pricing manufacturing costs. Our gross margins on revenues from sales of dermatology procedures equipment are lower than our gross margins on revenues from sales of dermatology recurring procedures and, as a result, the sales mix between dermatology recurring procedures and dermatology procedures equipment can affect the gross margin in any reporting period.

Engineering and Product Development

Engineering and product development expenses consist primarily of personnel expenses, including salaries and related benefits for employees in engineering, product development, regulatory and quality assurance functions. We typically use our employee, consultant and infrastructure resources across our engineering and product development programs.

We plan to incur engineering and product development expenses for the near future as we expect to continue our development that focuses on the application of our XTRAC system for the treatment of inflammatory skin disorders. As a result, we expect our engineering and product development expenses to remain similar to our fiscal year 2023 expenses.

Selling and Marketing

Selling and marketing expenses consist of market research and commercial activities related to the sale of our dermatology recurring procedures and dermatology procedures equipment sales, and salaries and related benefits and sales commissions for employees focused on these efforts. Other significant sales and marketing costs include conferences and trade shows, promotional and marketing activities, including direct and online marketing to the consumer and dermatologists, practice support programs, travel and training expenses.

We anticipate that our selling and marketing expenses will remain similar to our fiscal year 2023 expenses.

General and Administrative

General and administrative expenses consist primarily of personnel expenses, including salaries and related benefits, share-based compensation and travel expenses, for employees in executive, finance, information technology, legal and human resource functions. General and administrative expenses also include the cost of insurance, outside legal fees, accounting and other consulting services, audit fees from our independent registered public accounting firm, board of directors' fees and other administrative costs, such as corporate facility costs, including rent, utilities, depreciation and maintenance not otherwise included in cost of revenues.

We anticipate that our general and administrative expenses will remain similar to our fiscal year 2023 expenses.

Impairment of Goodwill

Impairment expense consists of an impairment charge related to goodwill resulting from the acquisition of the XTRAC and VTRAC businesses in 2015. We test goodwill for impairment during the fourth quarter of each year and whenever circumstances indicate the carrying value of goodwill may not be recoverable. Based on the assessment performed in the fourth quarter of 2023 in conjunction with the annual budgeting process, we recorded impairment for the amount by which the carrying value of the dermatology recurring procedures reporting unit exceeded its fair value. The impairment was primarily driven by a decline in projected cash flows, including revenues and profitability.

Loss on Debt Extinguishment

During the second quarter of 2023, we refinanced our Senior Term Facility with MidCap (see Note 10, **Long-term Debt** to the Notes to Consolidated Financial Statements). The new loan is considered substantially different from the original loan and, as such, we recorded a loss on debt extinguishment during the year ended December 31, 2023.

Interest Expense

Interest expense consists of cash interest payable under our debt facility and non-cash interest attributable to the amortization of deferred financing costs related to our indebtedness.

Interest Income

Interest income is earned on our cash and cash equivalents account balances.

Income Taxes

As of December 31, 2023, we had federal and state NOL carryforwards of \$205.2 million and \$63.6 million, respectively. The net operating loss carryforwards generated prior to 2018 began to expire for federal income tax purposes and begin expiring in 2030 for state income tax purposes. Federal and many state net operating losses generated in 2018 and into the future now have an indefinite life.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Results of Operations

Comparison of the Years ended December 31, 2023 and 2022

(in thousands)	Year Ended December 31,		Change	
	2023	2022	Dollar	Percentage
Revenues, net	\$ 33,358	\$ 36,161	\$ (2,803)	(8)%
Cost of revenues	14,897	14,393	504	4%
Gross profit	18,461	21,768	(3,307)	(15)%
Operating expenses:				
Engineering and product development	1,317	1,029	288	28%
Selling and marketing	12,956	15,301	(2,345)	(15)%
General and administrative	10,508	10,087	421	4%
Impairment of goodwill	2,284	—	2,284	100%
	27,065	26,417	648	2%
Loss from operations	(8,604)	(4,649)	(3,955)	85%
Other (expense) income:				
Interest expense	(1,640)	(926)	(714)	77%
Interest income	231	89	142	160%
Loss on debt extinguishment	(909)	—	(909)	100%
	(2,318)	(837)	(1,481)	177%
Loss before benefit from / (provision for) income taxes	\$ (10,922)	\$ (5,486)	\$ (5,436)	99%

Revenues

Revenues by Geography

The following table presents revenues by geography for the periods presented below:

(in thousands)	Year Ended December 31,		Change	
	2023	2022	Dollar	Percentage
Domestic	\$ 23,028	\$ 23,981	\$ (953)	(4)%
International	10,330	12,180	(1,850)	(15)%
Total revenues	\$ 33,358	\$ 36,161	\$ (2,803)	(8)%

Revenues by Product Type

The following table presents revenues by segment for the periods presented below:

(in thousands)	Year Ended December 31,		Change	
	2023	2022	Dollar	Percentage
Dermatology recurring procedures	\$ 21,530	\$ 23,025	\$ (1,495)	(6)%
Dermatology procedures equipment	11,828	13,136	(1,308)	(10)%
Total revenues	\$ 33,358	\$ 36,161	\$ (2,803)	(8)%

Dermatology Recurring Procedures

Recurring treatment revenues for the year ended December 31, 2023 were \$21.5 million, which we estimate is approximately 280,000 XTRAC treatments with prices between \$65 and \$95 per treatment, compared to recurring treatment revenues for the year ended December 31, 2022 of \$23.0 million, which we estimate is approximately 329,000 XTRAC treatments with prices between \$65 and \$95 per treatment. In connection with the launch of the TheraClear Acne Therapy System, there were 92 TheraClear devices placed in dermatologists' offices in the United States under our recurring procedures model as of December 31, 2023. Nominal revenue was earned from these devices during the year ended December 31, 2023.

Increases in procedures are dependent upon building market acceptance through marketing programs with our physician partners and their patients to show that the XTRAC procedures will be of clinical benefit and will be generally reimbursed by insurers. We believe that several factors have an impact on the prescribed use of XTRAC treatments for psoriasis and vitiligo patients. Specifically, we believe that there is a lack of awareness of the positive effects of XTRAC treatments among both sufferers and providers; and the treatment regimen, which can sometimes require up to 12 or more treatments, has limited XTRAC use to certain patient populations. We reduced our direct-to-patient advertising during 2023, which we believe contributed to the reduction in number of XTRAC treatments compared to 2022. Therefore, our strategy going forward is to increase our direct-to-patient program for XTRAC advertising in the United States, targeting psoriasis and vitiligo patients through a variety of media and through our use of social media such as Facebook and Twitter. We monitor the results of our advertising expenditures in this area to reach the more than 10 million patients in the United States we believe are afflicted with these diseases.

Revenues from dermatology recurring procedures are recognized as revenue over the estimated usage period of the agreed upon number of treatments, as the treatments are being used. As of December 31, 2023 and 2022, we deferred domestic net revenues of \$1.6 million and \$2.2 million, respectively, which will be recognized as revenue over the remaining usage period for the related placements.

Dermatology Procedures Equipment

For the year ended December 31, 2023, dermatology procedures equipment revenues were \$11.8 million. Internationally, we sold 68 systems (60 XTRAC and 8 VTRAC). Domestically, we sold 24 XTRAC systems for the year ended December 31, 2023.

For the year ended December 31, 2022, dermatology procedures equipment revenues were \$13.1 million. Internationally, we sold 100 systems (88 XTRAC and 12 VTRAC). Domestically, we sold 7 XTRAC systems for the year ended December 31, 2022.

The decrease in international equipment sales from 2022 to 2023 was primarily the result of a one-time sale during 2022 to our distributor in China of lasers that had originally been placed in physicians' offices under the dermatology recurring procedures model. The increase in domestic equipment sales from 2022 to 2023 was due to a temporary shift in strategy during 2023 whereby we offered physicians in the United States the option to purchase lasers rather than operate under the dermatology recurring procedures model.

Cost of Revenues and Gross Profit

The following tables present changes in our gross margin, by segment, for the periods presented below:

Dermatology Recurring Procedures

<i>(in thousands, except percentages)</i>	Year Ended December 31,		Change	
	2023	2022	Dollar	Percentage
Revenues	\$ 21,530	\$ 23,025	\$ (1,495)	(6)%
Cost of revenues	8,729	8,371	358	4%
Gross profit	\$ 12,801	\$ 14,654	\$ (1,853)	(13)%
Gross profit percentage	59.5%	63.6%		

The primary reason for the decrease in gross profit for the year ended December 31, 2023 was higher depreciation costs due to more XTRAC lasers and new TheraClear devices placed into service.

Dermatology Procedures Equipment

<i>(in thousands, except percentages)</i>	Year Ended December 31,		Change	
	2023	2022	Dollar	Percentage
Revenues	\$ 11,828	\$ 13,136	\$ (1,308)	(10)%
Cost of revenues	6,168	6,022	146	2%
Gross profit	\$ 5,660	\$ 7,114	\$ (1,454)	(20)%
Gross profit percentage	47.9%	54.2%		

The primary reasons for the decrease in gross profit for the year ended December 31, 2023 were lower recognition of previously deferred service revenue associated with service contracts assumed from Ra Medical in 2021 in connection with the Pharos asset acquisition, which is decreasing as the related service contracts expire, and an increase in domestic sales with longer warranty periods, leading to a greater amount of deferred revenue for those sales.

Engineering and Product Development

For the year ended December 31, 2023, engineering and product development expenses were \$1.3 million as compared to \$1.0 million for the year ended December 31, 2022. Engineering and product development costs during the year ended December 31, 2023 were higher primarily as a result of an increase in consulting expenses related to future enhancements of our devices.

Selling and Marketing

As of December 31, 2023, our sales and marketing personnel consisted of 35 full-time positions, compared to 63 full-time positions as of December 31, 2022, inclusive of a vice president of sales, a vice president of marketing and a vice president of relations, direct sales organization as well as an in-house call center staffed with patient advocates and a reimbursement group that provides necessary insurance information to our physician partners and their patients.

For the year ended December 31, 2023, sales and marketing expenses were \$13.0 million as compared to \$15.3 million for the year ended December 31, 2022. Sales and marketing expenses for the year ended December 31, 2023 were lower due to a reduction in salaries and commissions in connection with an overall reduction in the size of the sales force, in addition to a reduction in advertising costs.

General and Administrative

For the year ended December 31, 2023, general and administrative expenses increased to \$10.5 million from \$10.1 million for the year ended December 31, 2022. General and administrative expenses for the year ended December 31, 2023 were higher primarily due to higher legal and accounting costs and severance and other compensation-related expenses incurred as a result of the CEO transition, offset by a decrease in non-executive employee-related expenses, such as salaries and stock-based compensation expense.

Impairment of Goodwill

For the year ended December 31, 2023, impairment expense was \$2.3 million. The impairment charge relates to goodwill associated with the dermatology recurring procedures segment and was primarily driven by a decline in projected cash flows, including revenues and profitability. There was no impairment incurred during the year ended December 31, 2022.

Loss on Debt Extinguishment

During the second quarter of 2023, we refinanced our Senior Term Facility with MidCap (see Note 10, **Long-term Debt** to the Notes to Consolidated Financial Statements). The new loan is considered substantially different from the original loan and, as such, we recorded a loss on debt extinguishment of \$0.9 million during the year ended December 31, 2023. There was no such financing event or debt extinguishment during the year ended December 31, 2022.

Interest Expense

Interest expense is primarily attributable to our debt obligations. For the year ended December 31, 2023, interest expense increased to \$1.6 million from \$0.9 million for the year ended December 31, 2022. The increase was primarily the result of a higher interest rate on our variable rate Senior Term Facility entered into in September 2021 and the additional \$7.0 million borrowed under our Senior Term Facility on June 30, 2023.

Benefit from / (Provision for) Income Taxes

We recognized a benefit from income taxes of \$0.1 million for the year ended December 31, 2023 as compared to a provision for income taxes of \$0.1 million for the year ended December 31, 2022, which is comprised primarily of changes in the deferred tax liability related to goodwill.

Non-GAAP Financial Measures

We have determined to supplement our consolidated financial statements, prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”), presented elsewhere within this report, with certain non-GAAP measures of financial performance. These non-GAAP measures include non-GAAP gross profit, which excludes the non-cash expense of amortization of acquired intangible assets classified as cost of revenues, and non-GAAP adjusted EBITDA, “Earnings Before Interest, Taxes, Depreciation, and Amortization.”

These non-GAAP disclosures have limitations as an analytical tool, should not be viewed as a substitute for Gross Profit or Net Earnings (Loss) determined in accordance with U.S. GAAP, should not be considered in isolation or as a substitute for analysis of our results as reported under U.S. GAAP, nor are they necessarily comparable to non-GAAP performance measures that may be presented by other companies. We consider these non-GAAP measures in addition to our results prepared under current accounting standards, but they are not a substitute for, nor superior to, U.S. GAAP measures. These non-GAAP measures are provided to enhance readers’ overall understanding of our current financial performance and to provide further information for comparative purposes. This supplemental presentation should not be construed as an inference that the Company’s future results will be unaffected by similar adjustments to Gross Profit or Net Earnings (Loss) determined in accordance with U.S. GAAP. Specifically, we believe the non-GAAP measures provide useful information to management and investors by isolating certain expenses, gains and losses that may not be indicative of our core operating results and business outlook. In addition, we believe non-GAAP measures enhance the comparability of results against prior periods.

Reconciliation to the most directly comparable U.S. GAAP measure of all non-GAAP measures included in this Annual Report is as follows:

<i>(in thousands)</i>	Year Ended December 31,	
	2023	2022
Gross profit	\$ 18,461	\$ 21,768
Amortization of acquired intangible assets	1,861	2,031
Non-GAAP gross profit	\$ 20,322	\$ 23,799
Gross profit percentage	55.3%	60.2%
Non-GAAP gross profit percentage	60.9%	65.8%

<i>(in thousands)</i>	Year Ended December 31,	
	2023	2022
Net loss	\$ (10,830)	\$ (5,549)
Adjustments:		
Depreciation and amortization	5,553	5,293
Amortization of operating lease right-of-use asset	349	395
Loss on disposal of property and equipment	72	52
(Benefit from) / provision for income taxes	(92)	63
Interest income	(231)	(89)
Interest expense	1,640	926
Non-GAAP EBITDA	(3,539)	1,091
Impairment of goodwill	2,284	—
Stock-based compensation	1,303	1,466
Loss on debt extinguishment	909	—
Non-GAAP adjusted EBITDA	\$ 957	\$ 2,557

Liquidity and Capital Resources

As of December 31, 2023, we had cash and cash equivalents and restricted cash of \$8.1 million and an accumulated deficit of \$238.1 million. We used \$0.5 million and \$0.9 million in cash flows from operating activities during the years ended December 31, 2023 and 2022, respectively. We have historically incurred operating losses, and we anticipate that our operating losses will continue in the near term as we seek to expand our sales and marketing initiatives to support our growth in existing and new markets, invest funds in additional engineering and product development activities and utilize cash for other corporate purposes. Our primary sources of capital have been from borrowings under our debt facilities and sales of our products. As of December 31, 2023, we had \$15.0 million of borrowings outstanding under our debt facility with MidCap, which has a final maturity in June 2028.

In September 2021, we entered into a credit and security agreement with MidCap, also acting as the administrative agent, and the lenders identified therein and borrowed \$8.0 million in the form of a senior term loan. The term loan bore interest at LIBOR (with a LIBOR floor rate of 0.50%) plus 7.50% per year. In September 2022, we amended the facility to transition, upon the cessation of LIBOR, to one-month Secured Overnight Financing Rate (“SOFR”), or such other applicable period, plus 0.10%, with a floor of 0.50%. In June 2023, we amended the credit facility to: (i) refinance our existing \$8.0 million term loan, (ii) borrow an additional \$7.0 million, and (iii) provide for an additional \$5.0 million tranche that can be drawn under certain conditions in 2024. The facility matures on June 1, 2028. Borrowings under the credit facility bear interest at a rate per annum equal to the sum of (a) the greater of (i) the sum of (A) 30-day forward-looking term rate of one month SOFR, as published by CME Group Benchmark Administration Limited, from time to time, plus (B) 0.10%, and (ii) the applicable floor rate of 3.50%, with such sum reset monthly, and (b) 7.50%. We are obligated to make interest-only payments through June 2026. From July 2026 to maturity, we will make principal payments in 24 equal installments. We also amended and restated the existing warrant to allow MidCap to purchase 800,000 shares of our common stock at an exercise price of \$0.88 per share for a 10-year period ending June 30, 2033. The loan is senior to all other indebtedness and is secured by substantially all of our assets. We are subject to customary affirmative and negative covenants including a financial covenant based on minimum net revenue thresholds. Upon an event of default, including a covenant violation, all principal and interest are due on demand.

In February 2024, the parties amended the debt agreement in order to, among other things, revise the applicable minimum net revenue threshold financial covenant. For the periods ending March 31, 2024, June 30, 2024, September 30, 2024 and December 31, 2024, these amounts are set at \$29.0 million, \$29.25 million, \$29.5 million and \$30.0 million, respectively, and increasing to \$33.0 million as set forth in such amendment for the periods thereafter. Also, because we did not anticipate being in compliance with the applicable minimum net revenue threshold financial covenant for the period ended December 31, 2023 under the debt agreement, MidCap and the lenders in such amendment, agreed to grant a limited waiver of the foregoing event that had occurred prior to the effectiveness of such amendment and of any right the lenders may have to exercise any of their rights against us as a result.

In January 2022, we acquired certain assets related to the TheraClear devices from Theravant. Theravant is eligible to receive up to \$3.0 million in future earnout payments upon the achievement of certain annual net revenue milestones, up to \$20.0 million in future royalty payments based upon a percentage of gross profit from future domestic sales ranging from 10-20%, 25% of gross profit from international sales over the subsequent four-year period, and up to \$0.5 million in future milestone payments upon the achievement of certain development and commercialization related targets. Through December 31, 2023, we have incurred \$0.1 million of royalty and gross profit payments based on gross profit from domestic and international sales.

In October 2021, we entered into an equity distribution agreement with an investment bank under which we may sell up to \$11.0 million of our shares of common stock in registered “at-the-market” offerings. The shares will be offered at prevailing market prices, and we will pay commissions of up to 3.00% of the gross proceeds from the sale of shares sold through our agent, which may act as an agent and/or principal. We have no obligation to sell any shares under this agreement and may, at any time, suspend solicitations under this agreement. No shares of our common stock have been sold under this distribution agreement through December 31, 2023.

We cannot predict our revenues and expenses in the short term as a result of the COVID-19 pandemic, the ongoing Russia-Ukraine war, the Israel-Hamas conflict, supply chain disruptions, rising interest rates, and related responses by our customers and our ultimate consumers as a result thereof. Based on our current business plan, we believe that our cash and cash equivalents, combined with the anticipated revenues from the sale or use of our products and operating expense management, will be sufficient to satisfy our working capital needs, capital asset purchases, outstanding commitments and other liquidity requirements associated with our existing operations for at least the next 12 months following the date of the issuance of this Annual Report. However, if these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional debt or equity securities or enter into a new credit facility or another form of third-party funding or seek other debt financing. If we raise additional funds by issuing equity or equity-linked securities, our stockholders would experience dilution and any new equity securities could have rights, preferences, and privileges superior to those of holders of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. We cannot be assured that additional equity, equity-linked or debt financing will be available on terms favorable to us or our stockholders, or at all. It is also possible that we may allocate significant amounts of capital towards products or technologies for which market demand is lower than expected and, as a result, abandon such efforts. If we are unable to maintain our current financing or obtain adequate additional financing when we require it, or if we obtain financing on terms which are not favorable to us, or if we expend capital on products or technologies that are unsuccessful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may be required to delay the development, commercialization and marketing of our products.

The following table summarizes our sources and uses of cash for each of the periods presented:

<i>(in thousands)</i>	Year Ended December 31,	
	2023	2022
Cash (used in) provided by		
Operating activities	\$ (519)	\$ (924)
Investing activities	(5,019)	(4,367)
Financing activities	6,861	(500)
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 1,323</u>	<u>\$ (5,791)</u>

Operating Activities

Net cash used in operating activities was \$0.5 million for the year ended December 31, 2023, compared to cash used in operating activities of \$0.9 million for the year ended December 31, 2022. The decrease in cash used in operating activities for the year ended December 31, 2023 was primarily driven by a decrease in inventories and a consistent level of accounts receivable, offset by a higher net loss in the current year. We experienced an increase in accounts receivable in the prior year and had increased our inventories to avoid supply chain disruption.

Investing Activities

Net cash used in investing activities was \$5.0 million for the year ended December 31, 2023, compared to cash used in investing activities of \$4.4 million for the year ended December 31, 2022. The increase is primarily the result of an increase in capital assets as a result of the launch of the TheraClear Acne Therapy System, offset by the cash paid to acquire the TheraClear devices in 2022.

Financing Activities

Net cash provided by financing activities was \$6.9 million for the year ended December 31, 2023, compared to cash used in financing activities of \$0.5 million for the year ended December 31, 2022. The increase is primarily the result of the refinancing of the Senior Term Facility, pursuant to which we borrowed an additional \$6.9 million, net of financing costs.

Contractual Obligations and Commitments

Debt Obligations

In September 2021, we entered into an \$8.0 million secured borrowing facility with MidCap. In June 2023, we amended our credit facility with MidCap to: (i) refinance our existing \$8.0 million term loan, (ii) borrow an additional \$7.0 million, and (iii) provide for an additional \$5.0 million tranche that can be drawn under certain conditions in 2024. The facility matures on June 1, 2028. Borrowings under the credit facility bear interest at a rate per annum equal to the sum of (a) the greater of (i) the sum of (A) 30-day forward-looking term rate of one month SOFR, as published by CME Group Benchmark Administration Limited, from time to time, plus (B) 0.10%, and (ii) the applicable floor rate of 3.50%, with such sum reset monthly, and (b) 7.50%. We are obligated to make interest-only payments through June 2026. From July 2026 to maturity, we will make principal payments in 24 equal installments. The loan is senior to all other indebtedness and is secured by substantially all of our assets. We are subject to customary affirmative and negative covenants including a financial covenant based on minimum net revenue thresholds. Upon an event of default, including a covenant violation, all principal and interest are due on demand. The debt agreement was further amended in February 2024 to, among other things, revise the applicable minimum net revenue threshold financial covenant.

Operating Lease Obligations

We lease our facilities and certain IT and office equipment under non-cancellable operating leases with remaining lease terms of up to three years. Remaining lease obligations are \$0.6 million as of December 31, 2023, with payments of \$0.4 million due within the next year.

Contingent Consideration

Theravant, the seller of the TheraClear devices, is eligible to receive up to \$3.0 million in future earnout payments upon the achievement of certain annual net revenue milestones, up to \$20.0 million in future royalty payments based upon a percentage of gross profit from future domestic sales ranging from 10-20%, 25% of gross profit from international sales over the subsequent four-year period, and up to \$0.5 million in future milestone payments upon the achievement of certain commercialization related targets. Through December 31, 2023, we have incurred \$0.1 million of royalty and gross profit payments based on gross profit from domestic and international sales. As of December 31, 2023, we have estimated the future earnout payments at \$1.2 million, of which \$0.1 million is expected to be paid within the next year. Due to uncertainties associated with the development of a new product line and the use of estimates and assumptions to determine the fair value of the contingent consideration, the amount ultimately paid in connection with the earnout may differ from the estimated fair value.

Milestone Payments

In January 2022, we entered into a Development Agreement (the "Development Agreement") with Theravant. Under the Development Agreement, we will reimburse Theravant for costs incurred in further developing certain TheraClear technology and other healthcare products and methods for the medical aesthetic marketplace. In connection with the development of three devices, Theravant is eligible to receive \$0.5 million upon FDA clearance for each device and \$0.5 million upon achievement of certain net revenue targets for each device, aggregating to \$3.0 million of potential future milestone payments under the Development Agreement. The Development Agreement has a three-year term, unless terminated sooner by either party.

Impact of Inflation

We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the year ended December 31, 2023.

Critical Accounting Policies and Estimates

The preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, or GAAP, and the rules and regulations of the SEC requires us to make estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates and assumptions on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Although we believe our estimates and assumptions are reasonable when made, they are based upon information available to us at the time they are made. We evaluate our estimates and assumptions on an ongoing basis and, if necessary, make adjustments. Due to the risks and uncertainties involved in our business and evolving market conditions and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

We define our critical accounting policies as those accounting policies that are most important to the portrayal of our financial condition and results of operations and require our most difficult and subjective judgments. While our significant accounting policies are more fully described in “Note 2. Summary of Significant Accounting Policies” in our audited financial statements and related notes thereto appearing elsewhere in this Annual Report, we believe the following discussion addresses our most critical accounting policies.

Revenue Recognition

We have primarily two types of arrangements for our phototherapy treatment equipment from which we earn revenues from dermatology recurring procedures: (i) we place our lasers in a physician’s office at no charge to the physician, and generally charge the physician a fee for an agreed upon number of treatments; or (ii) we place our lasers in a physician’s office and charge the physician a fixed fee for a specified period of time not to exceed an agreed upon number of treatments; if that number is exceeded additional fees will have to be paid. Revenues attributable to these types of arrangements are accounted for under the guidance applicable to leases. These arrangements are similar to operating leases since we provide the customers limited arrangement rights to use the treatment equipment, the treatment equipment resides in the physician’s office and we may exercise the right to remove the equipment upon notice, under certain circumstances, while the physician controls the utility and output of such equipment during the term of the arrangement as it pertains to the use of access codes to treat the patients. For the first type of arrangement, sales of access codes are considered variable treatment code payments and are recognized as revenue over the estimated usage period of the agreed upon number of treatments. For the second type of arrangement, customers purchase access codes and revenue is recognized on a straight-line basis as the lasers are being used over the term specified in the agreement. Variable treatment code payments that will be paid only if the customer exceeds the agreed upon number of treatments are recognized only when such treatments are being exceeded and used.

We recognize revenue from dermatology procedures equipment sales when control of the promised good or service is transferred to our customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those good or services. Accordingly, we determine revenue recognition by applying the following steps:

- identification of the contract, or contracts, with a customer;
- identification of the performance obligations in the contract;
- determination of the transaction price;
- allocation of the transaction price to the performance obligations in the contract; and
- recognition of revenues when, or as, we satisfy a performance obligation.

A contract’s transaction price is allocated to each performance obligation and recognized as revenue when, or as, the performance obligation is satisfied, which is generally the point in time when the product is shipped or control is transferred for our dermatology procedures equipment sales. We sell to physicians in the United States and to third-party distributors outside the United States and do not provide return rights. Sales to distributors outside the United States are made in U.S. dollars. In addition, we provide a one to two-year warranty for systems sold in the United States. Terms of the of the product warranty differ amongst our third-party distributors outside the United States but are generally two years. These assurance-type warranties are not considered a separate performance obligation. We provide for the estimated cost to repair or replace products under any warranty at the time of sale. We also earn revenue from customers from services outside of their warranty term or annual service contracts. Revenue from these service-type warranties is recognized as the services are provided.

Contingent Consideration

The purchase price for certain assets acquired related to TheraClear devices during January 2022 includes earnout payments, or contingent consideration. Estimates that involve a significant level of estimation uncertainty include the valuation of contingent consideration, which was determined using forecasted financial information available at the acquisition date, a discount rate and various other assumptions as described in more detail in Note 3 to our consolidated financial statements. Due to uncertainties associated with the development of a new product line and the use of estimates and assumptions to determine the fair value of the contingent consideration, the amount ultimately paid in connection with the earnout may differ from the estimated fair value at the acquisition date. A revaluation of the contingent consideration would only be required if there is a significant change to the underlying valuation assumptions. The contingent consideration will be adjusted when the contingency is resolved and the consideration is paid or becomes payable. Any difference between the cash payment and the amount accrued for contingent consideration will result in an adjustment to the technology intangible asset.

During 2023, we revised our projections of expected revenues and gross profits to be earned from the sale of TheraClear devices. The change in projections was considered significant enough to warrant a revaluation of the contingent consideration. To calculate the fair value of the earnout at December 31, 2023, using Monte Carlo simulations, Company projections were utilized to develop expected revenues and gross profits based on the risk inherent in the projections using the Geometric-Brownian motion for the earnout periods and related earnout payments. Significant assumptions used in the Geometric-Brownian motion analysis include projected revenues, projected gross profit, risk free rate of return of 3.8%, revenue volatility of 15.0%, and a cost of equity of 10.0%. The fair value of the contingent consideration as of December 31, 2023 was estimated to be \$1.2 million, which resulted in a reduction in contingent consideration of \$7.4 million with a corresponding adjustment to the carrying value of the product technology intangible asset.

Goodwill and Intangible Impairments

As of December 31, 2023, we had \$6.5 million of goodwill related to the acquisitions of the XTRAC and VTRAC businesses in fiscal 2015. We evaluate the carrying value of goodwill during the fourth quarter of each year and whenever circumstances indicate the carrying value of goodwill may not be recoverable. The determination of the fair value of the reporting units to which the goodwill relates requires management to make estimates and assumptions. We organized our business into two operating segments, which also serve as our goodwill reporting units and are defined as Dermatology Recurring Procedures and Dermatology Procedures Equipment Sales. Our analysis employed the use of both a market and income approach, with the market approach given a 25% weighting and the income approach given a 75% weighting. Significant assumptions used in the income approach include growth and discount rates, profit margins and our weighted average cost of capital. We used historical performance and management estimates of future performance to determine profit margins and growth rates. Discount rates selected for each reporting unit varied. Our weighted average cost of capital included a review and assessment of market and capital structure assumptions. Based on the assessment performed in the fourth quarter of 2023 in conjunction with the budgeting process, we recorded a \$2.3 million impairment charge related to goodwill, which was the amount of the excess of the carrying value of the Dermatology Recurring Procedures reporting unit over its fair value. The impairment was primarily driven by a decline in projected cash flows, including revenues and profitability. Changes in our actual results and/or estimates or any of our other assumptions used in our analysis could result in a different conclusion.

All of our intangible assets are finite-lived assets, with amortization recorded over the estimated useful life on a straight-line basis. During the year ended December 31, 2023, we recorded a \$7.4 million reduction to the carrying value of the product technology intangible asset as a result of the revaluation of contingent consideration related to the purchase of the TheraClear devices. As of December 31, 2023 we had \$7.3 million of intangible assets. The finite-lived assets are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset group may not be recoverable. Our intangible assets are grouped into five categories: core technology, product technology, customer relationships, trade names and Pharos customer lists. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to the undiscounted cash flows attributable to the asset group. If the carrying amount of an asset group exceeds its undiscounted cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset group exceeds its fair value of the asset group.

Considerable management judgment is necessary to assess recoverable amounts of intangible assets and measure fair value of the intangible assets that were impaired as such measurements involve estimation of future revenues, royalty rates, profit margins and other cash flows. Changes in our actual results and/or estimates or any of our other assumptions used in our analysis could result in a different conclusion.

Sales and Use Taxes

We record state sales tax collected and remitted for our customers on dermatology procedures equipment sales on a net basis, excluded from revenue. Our sales tax expense that is not presently being collected and remitted for the recurring revenue business is recorded in general and administrative expenses within the consolidated statements of operations.

We believe our state sales and use tax accruals have been properly recognized such that, if our arrangements with customers are deemed more likely than not that we would not be exempt from sales tax in a particular state, the basis for measurement of the state sales and use tax is calculated in accordance with ASC 405, *Liabilities*, as a transaction tax. If and when we are successful in defending ourselves or in settling the sales tax obligation for a lesser amount, the reversal of this liability is to be recorded in the period the settlement is reached. However, the precise scope, timing and time period at issue, as well as the final outcome of any audit and actual settlement, remains uncertain.

In the ordinary course of business, we are, from time to time, subject to audits performed by state taxing authorities. These actions and proceedings are generally based on the position that the arrangements entered into by us are subject to sales and use tax rather than exempt from tax under applicable law. The states of New York and California have assessed us an aggregate of \$3.9 million including penalties and interest. The audits cover the period from March 2014 through November 2022. We received notification that an administrative state judge in New York issued an opinion finding in favor of the Company that the sale of XTRAC treatment codes was not taxable as sales tax with respect to that state's first assessment. This ruling covers \$1.4 million of the total \$3.9 million of assessments. The relevant taxing authority filed an appeal of the administrative law judge's finding and, following the submission of legal briefs by both sides and oral argument held in January 2022, on May 6, 2022, we received a written decision from the State of New York Appeals Tribunal ("Tribunal") overturning the favorable sales tax determination of the administrative law judge. We appealed the Tribunal's decision to the New York State Appellate Division ("Appellate Division"), and posted the required appellate bond in the form of cash collateral. Oral argument was held by the Appellate Division on January 18, 2024.

On March 8, 2024, we received a decision from the Appellate Division ruling against us in the matter of our sales tax appeal, affirming the Tribunal's ruling that our sale of XTRAC treatment codes is subject to sales tax. The Appellate Division concluded that, through the usage arrangements, our customers had possession of the laser devices and had a license and ability to use the laser devices. The Appellate Division also agreed with the Tribunal that the primary function analysis was not applicable in this matter. We will be filing a motion to appeal the Appellate Division's decision.

We are also in the administrative process of appeal with respect to the remaining \$2.5 million of assessments. If there is a determination that the true object of our recurring revenue model is not exempt from sales taxes and is not a prescription medicine, or we do not have other defenses where we prevail, we may be subject to sales taxes in those particular states for previous years and in the future, plus potential interest and penalties.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited financial statements appearing elsewhere in this Annual Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item 8 are included in this Annual Report and begin on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Limitations of Internal Control System

Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company have been detected. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), as of December 31, 2023. Based on that evaluation, management has concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management's Report on Internal Control over Financial Reporting

Our Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework established in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has determined that our internal control over financial reporting was effective as of December 31, 2023.

This Annual Report does not include an attestation report of our registered public accounting firm regarding our internal control over financial reporting. We are not required to have, nor have we engaged our independent registered public accounting firm to perform, an audit on our internal control over financial reporting pursuant to the rules of the SEC that permit us to provide only management's report in this Annual Report.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting in our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 8, 2024, we received a decision from the New York State Appellate Division ("Appellate Division") ruling against us in the matter of our sales tax appeal, affirming the State of New York Appeals Tribunal's ("Tribunal") ruling that our sale of XTRAC treatment codes is subject to sales tax. The Appellate Division concluded that, through the usage arrangements, our customers had possession of the laser devices and had a license and ability to use the laser devices. The Appellate Division also agreed with the Tribunal that the primary function analysis was not applicable in this matter. We will be filing a motion to appeal the Appellate Division's decision.

During the three months ended December 31, 2023, none of the directors or officers of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Consolidated balance sheets of STRATA Skin Sciences, Inc. and subsidiary as of December 31, 2023 and 2022, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years ended December 31, 2023 and 2022.

(a)(2) Financial Statement Schedules

None, as all information required in these schedules is included in the Notes to the Consolidated Financial Statements.

(a)(3) Exhibits

The exhibits listed under subsection (b) of this Item 15 are hereby incorporated by reference.

- 3.1 [Fifth Amended and Restated Certificate of Incorporation of the Company \(Incorporated by reference to Exhibit 3.1 contained in our Registration Statement on Form S-3 \(File No. 333-258814\), as filed on August 13, 2021\).](#)
- 3.2 [Fourth Amended and Restated Bylaws of the Company \(Incorporated by reference to Exhibit 3.2 contained in our Form 8-K current report as filed on January 8, 2016\).](#)
- 4.1 [Specimen Stock Certificate Incorporated by reference to our Registration Statement on Form S-1, as amended \(File No. 333-125517\), as filed on August 8, 2005\).](#)
- 4.2 [Description of Registrant's Securities \(attached hereto\).](#)
- 10.1* [Form of Indemnification Agreement for directors and executive officers. \(Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 17, 2014\).](#)
- 10.2* [2005 Stock Incentive Plan \(Incorporated by reference to our Registration Statement on Form S-1, as amended \(File No. 333-125517\), filed on August 8, 2005\).](#)
- 10.3* [Form of Incentive Stock Option Agreement. \(Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2015 filed on March 15, 2016\).](#)
- 10.4* [Form of Nonqualified Stock Option Agreement. \(Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2015 filed on March 15, 2016\).](#)
- 10.5* [STRATA Skin Sciences 2016 Omnibus Option Plan. \(Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 14, 2016\).](#)
- 10.6 [Securities Purchase Agreement dated as of March 30, 2018, between the Company and Accelmed \(Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on April 2, 2018\).](#)
- 10.7 [Securities Purchase Agreement dated as of March 30, 2018, between the Company and Broadfin \(Incorporated by reference to Exhibit 10.2 contained in our Current Report on Form 8-K, as filed on April 2, 2018\).](#)
- 10.8 [Securities Purchase Agreement dated as of March 30, 2018, between the Company and Sabby \(Incorporated by reference to Exhibit 10.3 contained in our Current Report on Form 8-K, as filed on April 2, 2018\).](#)
- 10.9 [Form of Registration Rights Agreement \(Incorporated by reference to Exhibit 10.4 contained in our Current Report on Form 8-K, as filed on April 2, 2018\).](#)
- 10.10 [Form of Leak-Out Agreement \(Incorporated by reference to Exhibit 10.5 contained in our Current Report on Form 8-K, as filed on April 2, 2018\).](#)
- 10.11 [Form of Subscription Agreement \(Incorporated by reference to Exhibit 10.7 contained in our Current Report on Form 8-K, as filed on April 2, 2018\).](#)

- 10.12* [Amended and Restated Strata Skin Sciences, Inc. 2016 Omnibus Incentive Plan \(Incorporated by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A, as filed on June 2, 2021\).](#)
- 10.13 [Sublease Agreement between Luigi Bormioli Corporation and the Company for office space at 5 Walnut Grove Drive, Horsham, PA 19044 \(Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on October 3, 2018\).](#)
- 10.14 [Settlement Agreement and Release, dated as of August 10, 2020, between STRATA Skin Sciences, Inc. and Ra Medical Systems, Inc. \(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 11, 2020\).](#)
- 10.15* [Employment Agreement, dated as of March 1, 2021, between Robert Moccia and STRATA Skin Sciences, Inc. \(incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on March 1, 2021\).](#)
- 10.16* [Form of Stock Option Agreement, dated as of March 1, 2021, between Robert Moccia and STRATA Skin Sciences, Inc. \(incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on March 1, 2021\).](#)
- 10.17* [Employment Agreement, dated as of October 4, 2021, between Christopher Lesovitz and STRATA Skin Sciences, Inc. \(incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on October 4, 2021\).](#)
- 10.18 [Form of Equity Distribution Agreement, dated October 15, 2021, between STRATA Skin Sciences, Inc. and Ladenburg Thalmann & Co. Inc. \(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 18, 2021\).](#)
- 10.19* [Form of Management Change of Control Severance Agreement \(incorporated by reference to Exhibit 10.79 to our Annual Report on Form 10-K for the year ended December 31, 2021\).](#)
- 10.20 [Credit and Security Agreement, dated as of September 30, 2021, as amended January 10, 2022, September 6, 2022 and June 30, 2023, among STRATA Skin Sciences, Inc., MidCap Financial Trust, as administrative agent, and the lenders identified therein. \(incorporated by reference to Exhibit A of Exhibit 10.1 to our Current Report on Form 8-K filed on June 30, 2023\).](#)
- 10.21 [Intellectual Property Security Agreement, dated as of September 30, 2021, between STRATA Skin Sciences, Inc. and MidCap Financial Trust. \(incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on October 4, 2021\).](#)
- 10.22 [Amended and Restated Warrant Agreement to Purchase Shares of the Common Stock of STRATA Skin Sciences, Inc., dated as of June 30, 2023, between STRATA Skin Sciences, Inc. and MidCap Funding XXVII Trust \(incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on July 6, 2023\).](#)
- 10.23 [Amended and Restated Registration Rights Agreement, dated as of June 30, 2023, between STRATA Skin Sciences, Inc. and MidCap Funding XXVII Trust \(incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on July 6, 2023\).](#)
- 10.24 [Amendment No. 3 to Credit and Security Agreement, dated as of June 30, 2023, among STRATA Skin Sciences, Inc., MidCap Financial Trust, as administrative agent, and the lenders identified therein \(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on June 30, 2023\).](#)
- 10.25 [Amendment No. 4 to Credit and Security Agreement, dated as of February 20, 2024, among STRATA Skin Sciences, Inc., MidCap Financial Trust, as administrative agent, and the lenders identified therein \(incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on February 21, 2024\).](#)
- 10.26 [Amendment No. 5 to Credit and Security Agreement, dated as of March 27, 2024, among STRATA Skin Sciences, Inc., MidCap Financial Trust, as administrative agent, and the lenders identified therein \(attached hereto\).](#)
- 10.27 [Asset Purchase Agreement, dated as of January 10, 2022, between STRATA Skin Sciences, Inc., Theravant Corporation and certain other parties thereto \(incorporated by reference as Exhibit 10.1 to our Current Report on Form 8-K dated January 10, 2022\).](#)
- 10.28 [Form of Development Agreement by and between Theravant Corporation and STRATA Skin Sciences, Inc. \(incorporation by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the period ended March 31, 2022\).](#)

10.29	Asset Purchase Agreement, dated as of August 16, 2021, between STRATA Skin Sciences, Inc. and Ra Medical Systems, Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 17, 2021).
10.30*	Form of Performance Stock Option Agreement (Non-Qualified Stock Option) (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the period ended March 31, 2022).
10.31*	Form of VWAP Performance Stock Option Agreement (Non-Qualified Stock Option) (incorporated by referenced to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the period ended March 31, 2022).
10.32	Letter Agreement, dated as of June 30, 2023, between STRATA Skin Sciences, Inc. and MidCap Financial Trust, as administrative agent (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on July 6, 2023).
10.33	Intellectual Property Security Agreement Supplement, dated July 5, 2023, between STRATA Skin Sciences, Inc. and MidCap Financial Trust (incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q for the period ended June 30, 2023).
10.34	Employment Separation Agreement and Release, dated as of October 30, 2023, between Robert Moccia and STRATA Skin Sciences, Inc. (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on October 30, 2023).
10.35	Employment Agreement, dated as of October 30, 2023, between Dolev Rafaeli and STRATA Skin Sciences, Inc. (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on October 30, 2023).
10.36	Form of Stock Option Agreement between Dolev Rafaeli and STRATA Skin Sciences, Inc. (incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on October 30, 2023).
10.37	Retention Agreement, dated October 30, 2023, between Chris Lesovitz and STRATA Skin Sciences, Inc. (incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on October 30, 2023).
10.38	Letter agreement, dated as of February 20, 2024, between STRATA Skin Sciences, Inc. and MidCap Financial Trust, as administrative agent (incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on February 21, 2024).
10.39	STRATA Skin Sciences, Inc. Clawback Policy (attached hereto)
23.1	Consent of Marcum, LLP
31.1	Rule 13a-14(a) Certificate of Chief Executive Officer
31.2	Rule 13a-14(a) Certificate of Chief Financial Officer
32.1**	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Indicates management contract or compensatory plan

** The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

STRATA SKIN SCIENCES, INC.

Date: March 27, 2024

By: /s/ Dolev Rafaeli
Dolev Rafaeli
Chief Executive Officer and Director (principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Dolev Rafaeli</u> Dolev Rafaeli	President, Chief Executive Officer, and Director (<i>Principal Executive Officer</i>)	March 27, 2024
<u>/s/ Christopher Lesovitz</u> Christopher Lesovitz	Chief Financial Officer (<i>Principal Financial Officer and Financial Officer</i>)	March 27, 2024
<u>/s/ Uri Geiger</u> Uri Geiger	Director and Chairperson of the Board of Directors	March 27, 2024
<u>/s/ Samuel Rubinstein</u> Samuel Rubinstein	Director	March 27, 2024
<u>/s/ Dr. Irit Yaniv</u> Dr. Irit Yaniv	Director	March 27, 2024
<u>/s/ Wayne Cafran</u> Wayne Cafran	Director	March 27, 2024

STRATA SKIN SCIENCES, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
STRATA Skin Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of STRATA Skin Sciences, Inc. and Subsidiary (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sales and Use Tax Liabilities:

As discussed in Note 11 to the consolidated financial statements, the Company recognizes sales tax liabilities, including interest and penalties, for its domestic recurring revenue in those states which management determines are more-likely-than-not ("MLTN") non-exempt from sales tax. Such amounts are accounted for as transaction tax liabilities that are extinguished upon payment or settlement. The Company recognizes use tax liabilities, including interest and penalties, for those states that management determines are MLTN to be exempt from sales tax obligations. The Company's sales tax expense that is not presently being collected and remitted for its domestic recurring revenue are recorded as general and administrative expenses. The Company is undergoing sales tax audits in two state jurisdictions which are each in the process of appeal.

We identified the accounting for sales and use tax liabilities as a critical audit matter due to the audit effort relating to the following:

- The Company utilized specialists in prior years to assist in determining MLTN conclusions, and such analysis has been updated in the current year by management and counsel.
- Complexity in the interpretation of relevant tax laws in various states requires significant management and auditor judgment.
- The extent of specialized skill and knowledge and consultation outside of the engagement team required to assess the appropriateness of management's determinations.

Our principal audit procedures related to the Company's accounting for sales and use tax liabilities included the following:

- We evaluated management's significant accounting policies related to accounting for sales and use tax liabilities for reasonableness.
- We involved our firm's tax professionals and subject-matter-experts, with specialized skills and knowledge, who assisted in assessing the Company's interpretation of the relevant tax laws.
- We inspected correspondence and determinations from relevant state taxing authorities for those states undergoing sales tax audits.
- We tested the underlying data of management's calculations and analyzed the expiration of statutes of limitations and tax rates.

Goodwill:

As discussed in Note 2 to the consolidated financial statements, goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in a business combination. Goodwill is tested for impairment at least annually at the reporting unit level. Management bypassed the qualitative impairment assessment (step zero) and performed a quantitative impairment assessment. The Company used a combination of the market and income approaches to determine the estimated fair value of its reporting units as of December 31, 2023.

We identified the annual goodwill impairment test as a critical audit matter due to the audit effort relating to the following:

- The determination of the fair value of the reporting unit requires management to make significant estimates and assumptions related to forecasted revenue growth rates, estimated expenses and discount rates. Such estimates and assumptions were challenging to test as they required forward looking assumptions with a high degree of subjectivity.
- The extent of specialized skill and knowledge and consultation outside of the engagement team required to assess the appropriateness of management's valuation assumptions.

Our principal audit procedures related to the Company's goodwill impairment test included the following:

- We evaluated management's significant accounting policies related to goodwill impairment for reasonableness.
- We obtained an understanding and evaluated the reasonableness of management's forecasts of future revenue and estimated expenses by comparing these forecasts to historical operating results of the Company by applying procedures to test the financial inputs used in the income approach, including sensitizing management's cash flow forecasts.
- We involved our firm's valuation professionals, with specialized skills and knowledge, who assisted in assessing assumptions utilized under the income and market approaches. Such assumptions that were evaluated included the discount rate, selected comparable companies, market multiples, residual growth rate, control premium and market capitalization reconciliation.

Contingent Consideration:

As discussed in Note 3 to the consolidated financial statements, the Company acquired certain assets related to the TheraClear devices from Theravant Corporation ("Theravant"). The purchase price included an initial cash payment, issuance of common stock and contingent consideration. The contingent consideration is accounted for as a contingent liability under ASC 450, *Contingencies*.

We identified the valuation of the contingent consideration as a critical audit matter due to the audit effort relating to the following:

- The determination of the estimate of the contingent consideration liability requires management to make significant estimates and assumptions related to forecasted revenue growth rates, estimated expenses, royalty rate and discount rates. Such estimates and assumptions were challenging to test as they required forward looking assumptions with a high degree of subjectivity.
- The extent of specialized skill and knowledge and consultation outside of the engagement team required to assess the appropriateness of management's valuation assumptions.

Our principal audit procedures related to the Company's estimate of the contingent consideration included the following:

- We evaluated management's significant accounting policies related to accounting for contingent consideration for reasonableness.
- We obtained an understanding and evaluated the reasonableness of management's forecasts of future revenue and estimated expenses by applying procedures to test the financial inputs used in the income approach, including sensitizing management's cash flow forecasts.
- We involved our firm's valuation professionals, with specialized skills and knowledge, who assisted in assessing assumptions utilized under the income approach. Such assumptions that were evaluated included the appropriateness of valuation model used, discount rate, selected comparable companies, revenue volatility, cost of equity and royalty rate.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2019.

Philadelphia, Pennsylvania

March 27, 2024

STRATA Skin Sciences, Inc. and Subsidiary
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,784	\$ 5,434
Restricted cash	1,334	1,361
Accounts receivable, net of allowance for credit losses of \$222 and \$382 at December 31, 2023 and 2022, respectively	4,440	4,471
Inventories	2,673	3,095
Prepaid expenses and other current assets	312	691
Total current assets	15,543	15,052
Property and equipment, net	11,778	9,950
Operating lease right-of-use assets	626	975
Intangible assets, net	7,319	17,394
Goodwill	6,519	8,803
Other assets	231	98
Total assets	\$ 42,016	\$ 52,272
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,343	\$ 3,425
Accrued expenses and other current liabilities	6,306	6,555
Deferred revenues	2,120	2,778
Current portion of operating lease liabilities	352	355
Current portion of contingent consideration	53	313
Total current liabilities	12,174	13,426
Long-term debt, net	15,044	7,476
Deferred revenues and other liabilities	552	314
Deferred tax liability	186	306
Operating lease liabilities, net of current portion	237	610
Contingent consideration, net of current portion	1,135	8,309
Total liabilities	29,328	30,441
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Series C convertible preferred stock, \$0.10 par value; 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$0.001 par value; 150,000,000 shares authorized; 35,060,920 and 34,723,046 shares issued and outstanding at December 31, 2023 and 2022, respectively	35	35
Additional paid-in capital	250,711	249,024
Accumulated deficit	(238,058)	(227,228)
Total stockholders' equity	12,688	21,831
Total liabilities and stockholders' equity	\$ 42,016	\$ 52,272

The accompanying notes are an integral part of these consolidated financial statements.

STRATA Skin Sciences, Inc. and Subsidiary
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Revenues, net	\$ 33,358	\$ 36,161
Cost of revenues	14,897	14,393
Gross profit	<u>18,461</u>	<u>21,768</u>
Operating expenses:		
Engineering and product development	1,317	1,029
Selling and marketing	12,956	15,301
General and administrative	10,508	10,087
Impairment of goodwill	2,284	—
	<u>27,065</u>	<u>26,417</u>
Loss from operations	<u>(8,604)</u>	<u>(4,649)</u>
Other (expense) income:		
Interest expense	(1,640)	(926)
Interest income	231	89
Loss on debt extinguishment	(909)	—
	<u>(2,318)</u>	<u>(837)</u>
Loss before benefit from / (provision for) income taxes	(10,922)	(5,486)
Benefit from / (provision for) income taxes	92	(63)
Net loss	<u>\$ (10,830)</u>	<u>\$ (5,549)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.16)</u>
Weighted average shares of common stock outstanding, basic and diluted	<u>34,920,291</u>	<u>34,712,246</u>

The accompanying notes are an integral part of these consolidated financial statements.

STRATA Skin Sciences, Inc. and Subsidiary
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-in- Capital	Accumulated Deficit	Total Stockholder's Equity
	Shares	Amount			
Balance at January 1, 2022	34,364,679	\$ 34	\$ 247,059	\$ (221,679)	\$ 25,414
Stock-based compensation expense	—	—	1,466	—	1,466
Issuance of common stock for acquisition	358,367	1	499	—	500
Net loss	—	—	—	(5,549)	(5,549)
Balance at December 31, 2022	<u>34,723,046</u>	<u>35</u>	<u>249,024</u>	<u>(227,228)</u>	<u>21,831</u>
Stock-based compensation expense	—	—	1,303	—	1,303
Issuance of restricted stock	337,874	—	—	—	—
Modification of common stock warrants	—	—	384	—	384
Net loss	—	—	—	(10,830)	(10,830)
Balance at December 31, 2023	<u><u>35,060,920</u></u>	<u><u>\$ 35</u></u>	<u><u>\$ 250,711</u></u>	<u><u>\$ (238,058)</u></u>	<u><u>\$ 12,688</u></u>

The accompanying notes are an integral part of these consolidated financial statements.

STRATA Skin Sciences, Inc. and Subsidiary
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (10,830)	\$ (5,549)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,553	5,293
Impairment expense	2,284	—
Amortization of operating lease right-of-use assets	349	395
Amortization of deferred financing costs and debt discount	140	157
Change in allowance for credit losses	(110)	107
Stock-based compensation expense	1,303	1,466
Loss on debt extinguishment	909	—
Loss on disposal of property and equipment	72	52
Deferred income taxes	(120)	40
Changes in operating assets and liabilities:		
Accounts receivable	141	(1,145)
Inventories	689	(1,340)
Prepaid expenses and other assets	246	(111)
Accounts payable	(100)	603
Accrued expenses and other liabilities	(197)	229
Deferred revenues	(472)	(644)
Operating lease liabilities	(376)	(477)
Net cash used in operating activities	<u>(519)</u>	<u>(924)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(5,019)	(3,736)
Cash paid in connection with TheraClear asset acquisition	—	(631)
Net cash used in investing activities	<u>(5,019)</u>	<u>(4,367)</u>
Cash flows from financing activities:		
Proceeds from long-term debt	7,000	—
Payment of deferred financing costs	(97)	—
Payment of contingent consideration	(42)	(500)
Net cash provided by (used in) financing activities	<u>6,861</u>	<u>(500)</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	1,323	(5,791)
Cash, cash equivalents and restricted cash at beginning of year	6,795	12,586
Cash, cash equivalents and restricted cash at end of year	<u>\$ 8,118</u>	<u>\$ 6,795</u>
Supplemental disclosure of cash flow information:		
Cash paid during the year for interest	\$ 1,415	\$ 744
Cash paid during the year for income taxes	\$ 22	\$ 19
Supplemental schedule of non-cash operating, investing and financing activities:		
Modification of common stock warrants	\$ 384	\$ —
Transfer of property and equipment to inventories	\$ 267	\$ 463
Change in intangible assets and fair value of contingent consideration	\$ 7,374	\$ —
Accrued exit fee recorded as debt discount	\$ 450	\$ —
Accrued payment of contingent consideration	\$ 18	\$ —
Inventories acquired in connection with TheraClear asset acquisition	\$ —	\$ 71
Intangible assets acquired in connection with TheraClear asset acquisition	\$ —	\$ 10,182
Contingent consideration issued in connection with TheraClear asset	\$ —	\$ 9,122
Common stock issued in connection with TheraClear asset acquisition	\$ —	\$ 500
Change in operating lease right-of-use assets and liabilities due to new and amended leases	\$ —	\$ 732

The accompanying notes are an integral part of these consolidated financial statements.

**STRATA Skin Sciences, Inc. and Subsidiary
Notes to Consolidated Financial Statements**

1. Organization and Nature of Business

STRATA Skin Sciences, Inc. (the “Company”) is a medical technology company in dermatology dedicated to developing, commercializing and marketing innovative products for the treatment of dermatologic conditions. Its products include the XTRAC® and Pharos® excimer lasers and VTRAC® lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions. In January 2022, the Company acquired the TheraClear Acne Therapy System to broaden its opportunities with expansion potential in the acne care market. The Company markets the device under the brand name TheraClear® X.

Post-COVID-19 Pandemic

Since March 2020, the global pandemic related to a new strain of coronavirus (“COVID-19”) has negatively impacted business conditions in the industry in which the Company operates, disrupted global supply chains, constrained workforce participation and created significant volatility and disruption of financial markets. The pandemic led to the suspension of elective procedures in the U.S. and to the temporary closure of many physician practices, which are the Company’s primary customers. While most offices have reopened, some physician practices closed and never reopened. Accordingly, the COVID-19 pandemic and its variants have negatively impacted the Company’s operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frames and those of its primary customers. It has also negatively impacted the Company’s supply chains and transport, customer behavior and staffing.

Impact of Russia-Ukraine War

Prior to the outbreak of the Russia-Ukraine War, Ukraine was the largest exporter of noble gases including neon, krypton, and xenon and has historically been the source of a significant amount of gas supplied to the Company by its contract suppliers. Neon gas is essential to the proper functioning of the Company’s lasers. The Company’s suppliers have been resourceful in continuing to supply gases to the Company but cannot assure the Company that the supply will remain uninterrupted. The reduced supply and ongoing conflict have also impacted the price of gas worldwide. Additionally, the Creating Helpful Incentives to Produce Semiconductors and Science Act of 2022 has led to a further tightening of rare gas supplies as semiconductor chip manufacturers reconfigure their supply chains to address the need to secure their own supplies of rare gases for use in the manufacture of computer chips.

Liquidity and Going Concern

The Company has been negatively impacted by the COVID-19 pandemic, has historically experienced recurring losses, has been dependent on raising capital from the sale of securities in order to continue to operate and has been required to restrict cash for potential sales tax liabilities (see Note 11). In October 2021, the Company entered into an equity distribution agreement with an investment bank under which the Company may sell up to \$11.0 million of its common stock in registered “at-the-market” offerings. In June 2023, the Company amended its credit facility with MidCap Financial Trust to: (i) refinance its existing \$8.0 million term loan, (ii) borrow an additional \$7.0 million, and (iii) provide for an additional \$5.0 million tranche that can be drawn under certain conditions in 2024. Management believes that the Company’s cash and cash equivalents, combined with the anticipated revenues from the sale or use of its products and operating expense management, will be sufficient to satisfy the Company’s working capital needs, capital asset purchases, outstanding commitments and other liquidity requirements associated with its existing operations for at least the next 12 months following the date of the issuance of these consolidated financial statements. However, market conditions, including the negative impact of the COVID-19 pandemic, the Russia-Ukraine War, and the Israel-Hamas conflict on the financial markets, supply chain disruptions, customer behavior, and rising interest rates, could interfere with the Company’s ability to access financing and on favorable terms.

STRATA Skin Sciences, Inc. and Subsidiary
Notes to Consolidated Financial Statements

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements are presented in U.S. dollars and have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Updates (“ASUs”) of the Financial Accounting Standards Board (“FASB”). The accompanying consolidated financial statements include the accounts of the Company and Photomedex India Private Limited, its wholly-owned subsidiary in India. No operating activities have occurred within the Company’s subsidiary as of and during the years ended December 31, 2023 and 2022.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation, including the reclassification of lasers-in-process from raw materials and work-in-process inventories and finished goods inventories to property and equipment, net on the consolidated balance sheet.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. The Company’s significant estimates and judgments include revenue recognition with respect to deferred revenues and the contract term and valuation allowances of accounts receivable, inputs used when evaluating goodwill for impairment, inputs used in the valuation of contingent consideration, state sales and use tax accruals, the estimated useful lives of intangible assets, and the valuation allowance related to deferred tax assets. Actual results could differ from those estimates.

Concentrations of Credit Risk and Major Customers

The Company’s cash is held on deposit in demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of \$0.3 million per depositor, per FDIC-insured bank, per ownership category. Management has reviewed the financial statements of this institution and believes it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little credit risk to the Company.

Financial instruments that potentially subject the Company to concentrations of credit risk principally consist of cash equivalents and accounts receivable. The Company limits its credit risk associated with cash equivalents by placing investments in highly-rated money market funds. The Company limits its credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary, but it does not require collateral to secure amounts owed by its customers.

The Company had one and two customers, international distributors, from which it earns dermatology recurring procedures and dermatology procedures equipment revenues, that accounted for 10% or more of the Company’s revenues for the years ended December 31, 2023 and 2022, respectively. Revenues from these customers were \$3.3 million and \$8.5 million, or 10% and 23%, of total net revenues during the years ended December 31, 2023 and 2022, respectively. Accounts receivable associated with these customers was nil as of December 31, 2023 and \$0.5 million, or 11%, of net accounts receivable as of December 31, 2022. One other customer had \$0.7 million, or 16.5%, of net accounts receivable as of December 31, 2023. No other customer represented more than 10% of total accounts receivable as of December 31, 2022.

Cash and Cash Equivalents

The Company considers all highly-liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2023 and 2022, cash equivalents consisted of credit card transactions with settlement terms of less than five days.

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Restricted Cash

As discussed more fully in Note 11, an administrative state judge in the State of New York issued an opinion in January 2021 finding in favor of the Company that the sale of XTRAC treatment codes was not taxable as sales tax with respect to that state's first assessment. The relevant taxing authority filed an appeal of the administrative law judge's finding and, following the submission of legal briefs by both sides and oral argument held in January 2022, on May 6, 2022, the Company received a written decision from the State of New York Tax Appeals Tribunal ("Tribunal") overturning the favorable sales tax determination of the administrative law judge. The Company appealed the Tribunal's decision to the New York State Appellate Division ("Appellate Division"), and posted the required appellate bond in the form of cash collateral. Oral argument was held by the Appellate Division on January 18, 2024.

On March 8, 2024, the Company received a decision from the Appellate Division ruling against it in the matter of its sales tax appeal, affirming the Tribunal's ruling that the Company's sale of XTRAC treatment codes is subject to sales tax. The Appellate Division concluded that, through the usage arrangements, the Company's customers had possession of the laser devices and had a license and ability to use the laser devices. The Appellate Division also agreed with the Tribunal that the primary function analysis was not applicable in this matter. The Company will be filing a motion to appeal the Appellate Division's decision.

The cash collateral is recorded as restricted cash on the consolidated balance sheets as of December 31, 2023 and 2022. The following table provides a reconciliation of the components of cash, cash equivalents and restricted cash reported in the Company's consolidated balance sheets to the total of the amount presented in the consolidated statements of cash flows (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents	\$ 6,784	\$ 5,434
Restricted cash	1,334	1,361
Total cash, cash equivalents and restricted cash presented in the consolidated statements of cash flows	\$ 8,118	\$ 6,795

Accounts Receivable and Allowance for Credit Losses

Accounts receivable primarily relates to amounts due from customers, which are typically due within 30 to 90 days from invoice date. The Company provides credit to its customers in the normal course of business and maintains allowances for expected credit losses over the remaining contractual lives of its receivables, considering customer financial condition, historical loss experience with customers, current market economic conditions and forecasts of future economic conditions when appropriate. The Company does not require collateral or other security for accounts receivable. The Company also maintains allowances for estimated losses resulting from amounts deemed to be uncollectible from its customers. These allowances are for specific amounts on certain customer accounts based on facts and circumstances determined on a case-by-case basis. The Company writes off accounts receivable when they are considered uncollectible, and payments subsequently received on such receivables are credited to bad debt expense. The Company does not recognize interest accruing on accounts receivable past due.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined based on purchased cost for raw materials and all production cost related to the laser manufacturing process (labor and indirect manufacturing cost, including sub-contracted work components) for work-in-process and finished goods is classified as inventory. For the Company's products, cost is determined on the first-in, first-out method. Work-in-process is immaterial, given the typically short manufacturing cycle and therefore, is disclosed in conjunction with raw materials.

The Company's equipment for the treatment of skin disorders (e.g. the XTRAC) will either (i) be placed in a physician's office and remain the property of the Company (at which date such equipment is transferred to property and equipment) or (ii) be sold to distributors or physicians directly. The cost to build a laser for sale is accumulated in inventory, and the cost to build a laser for placement is accumulated in property and equipment.

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Reserves for slow-moving and obsolete inventories are provided based on historical experience and product demand. Management evaluates the adequacy of these reserves periodically based on forecasted sales and market trends.

Property and Equipment, net

Property and equipment are recorded at cost less accumulated depreciation and amortization. Maintenance and repairs are charged to expense as incurred and costs of improvements and renewals are capitalized. Upon retirement or disposition, the applicable property and equipment amounts are deducted from the accounts and any gain or loss is recorded in the consolidated statements of operations. Depreciation and amortization are recognized using the straight-line method based on the estimated useful lives of the related assets. The Company uses an estimated useful life of three years for computers, hardware and software, five years for machinery and equipment and seven years for furniture and fixtures and the lesser of the useful life or lease term for leasehold improvements.

Intangible Assets

Intangible assets consist of core technology, product technology, customer relationships, trademarks and distribution rights. Intangible assets are amortized over the period of estimated benefit using the straight-line method and estimated useful lives ranging from three to 12 years.

Goodwill

Goodwill is the excess of the cost of an acquired entity over the net amounts assigned to tangible and intangible assets acquired and liabilities assumed. Goodwill is not amortized, but is subject to an annual impairment test. The Company has two reporting units and goodwill is allocated to the reporting units (see Note 15).

The Company performs its goodwill impairment test on an annual basis in the fourth quarter of each fiscal year or more frequently if changes in circumstances or the occurrence of events suggest that an impairment exists. If the fair value of the reporting unit is less than its carrying value, an impairment loss is recorded for the amount by which the carrying amount of the reporting unit, including goodwill, exceeds its fair value, limited to the total amount of goodwill allocated to that reporting unit. In conjunction with the annual budgeting process during the fourth quarter of 2023 and using data collected since the official launch of the TheraClear devices, the Company reduced its projected earnings from TheraClear devices (see Note 3). As a result, the Company bypassed the qualitative assessment of goodwill impairment and performed a quantitative assessment by comparing the fair value of each reporting unit with its carrying amount. The Company recorded a \$2.3 million impairment charge related to goodwill, which was the amount of the excess of the carrying value of the dermatology recurring procedures reporting unit over its fair value. The impairment was primarily driven by a decline in projected cash flows, including revenues and profitability. The fair values of the reporting units were determined using both a market and income approach, with the market approach given a 25% weighting and the income approach given a 75% weighting. Significant assumptions used in the income approach include growth and discount rates, profit margins and the Company's weighted average cost of capital. Historical performance and management estimates of future performance were used to determine profit margins and growth rates.

The impairment charge is included in impairment of goodwill within the consolidated statement of operations for the year ended December 31, 2023. The dermatology procedures equipment reporting unit was not identified as having impairment for the year ended December 31, 2023. The Company's annual goodwill impairment test resulted in no impairment charge during the year ended December 31, 2022.

Impairment of Long-Lived Assets and Intangibles

The Company reviews its long-lived assets and intangible assets subject to amortization for impairment whenever events or changes in circumstances indicate the carrying amount of an asset group may not be recoverable. Recoverability of assets held and used is measured by comparison of the carrying amount of an asset group to future net cash flows expected to be generated by the asset group. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the fair value of the asset group, less costs to sell. The Company did not record any charges related to asset impairment during the years ended December 31, 2023 and 2022.

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Fair Value Measurements

The Company measures financial assets and liabilities at fair value at each reporting period using a fair value hierarchy that requires the use of observable inputs and minimizes the use of unobservable inputs. The Company defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value is estimated by applying the following hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

- Level 1 – quoted market prices in active markets for identical assets or liabilities.
- Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – inputs that are generally unobservable and typically reflect the Company’s estimate of assumptions that market participants would use in pricing the asset or liability.

Accrued Warranty Costs

The Company offers a standard warranty on product sales generally for a one to two-year period, however, the Company has offered longer warranty periods, ranging from three to four years, in order to meet competition or meet customer demands. The Company provides for the estimated cost of the future warranty claims on the date the product is sold.

The activity in the warranty accrual during the years ended December 31, 2023 and 2022 is summarized as follows (in thousands):

	December 31,	
	2023	2022
Balance, beginning of year	\$ 207	\$ 79
Additions	237	246
Expirations and claims satisfied	(141)	(118)
Total	303	207
Less current portion within accrued expenses and other current liabilities	(180)	(136)
Balance within deferred revenues and other liabilities	\$ 123	\$ 71

Debt Issuance Costs

The Company capitalizes direct costs incurred to obtain debt financing and amortizes these costs to interest expense over the term of the debt using the effective interest method. These costs are recorded as a debt discount and are netted against the related debt on the Company’s consolidated balance sheets.

Revenue Recognition

Revenues from the Company’s dermatology recurring procedures customers are earned by providing physicians with its laser products and charging the physicians a fee for a fixed number of treatment sessions or a fixed fee for a specified period of time not to exceed an agreed upon number of treatments; if that number is exceeded additional fees will have to be paid. The placement of the laser products at physician locations represents embedded leases which are accounted for as operating leases. For the lasers placed-in service under these arrangements, the terms of the domestic arrangements are generally 36 months with automatic one-year renewals and include a termination clause that can be effected at any time by either party with 30 to 60 day notice. Amounts paid are generally non-refundable. Sales of access codes for a fixed number of treatment sessions are considered variable treatment code payments and are recognized as revenue over the estimated usage period of the agreed upon number of treatments. Sales of access codes for a specified period of time are recognized as revenue on a straight-line basis as the lasers are being used over the term specified in the agreement. Variable treatment code payments that will be paid only if the customer exceeds the agreed upon number of treatments are recognized only when such treatments are being exceeded and used. Internationally, the Company generally sells access codes for a fixed amount on a monthly basis to its distributors and the terms are generally 48 months, with termination in the event of the customers’ failure to remit payments timely, and include a potential buy-out at the end of the term of the contract. Currently, this is the only foreign recurring revenue. Prepaid amounts recorded in deferred revenue and customer deposits recorded in accounts payable are recognized as revenue over the lease term in the patterns described above. Pricing is fixed with the customer. With respect to lease and non-lease components, the Company adopted the practical expedient to account for the arrangement as a single lease component.

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Revenues from the Company's dermatology procedures equipment are recognized when control of the promised goods or services is transferred to its customers or distributors, in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. Accordingly, the Company determines revenue recognition through the following steps:

- identification of the contract, or contracts, with a customer;
- identification of the performance obligations in the contract;
- determination of the transaction price;
- allocation of the transaction price to the performance obligations in the contract; and
- recognition of revenue when, or as, performance obligations are satisfied.

Accounting for the Company's contracts involves the use of significant judgments and estimates including determining the separate performance obligations, allocating the transaction price to the different performance obligations and determining the method to measure the entity's performance toward satisfaction of performance obligations that most faithfully depicts when control is transferred to the customer. The Company allocates the contract's transaction price to each performance obligation using the Company's best estimate of the standalone selling price for each distinct good or service in the contract. The Company maximizes the use of observable inputs by beginning with average historical contractual selling prices and adjusting as necessary and on a consistent and rational basis for other inputs such as pricing trends, customer types, volumes and changing cost and margins.

Revenues from dermatology procedures equipment are recognized when control of the promised products is transferred to either the Company's distributors or end-user customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those products (the transaction price). Control transfers to the customer at a point in time. To indicate the transfer of control, the Company must have a present right to payment and legal title must have passed to the customer. The Company ships most of its products FOB shipping point, and as such, the Company primarily transfers control and records revenue upon shipment. From time to time the Company will grant certain customers, for example governmental customers, FOB destination terms, and the transfer of control for revenue recognition occurs upon receipt. The Company has elected to recognize the cost of freight and shipping activities as fulfillment costs. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying goods are transferred to the customer. The related shipping and freight charges incurred by the Company are included in cost of revenues.

The following table presents the Company's net revenues disaggregated by dermatology recurring procedures and dermatology procedures equipment (in thousands):

	Year Ended	
	December 31,	
	2023	2022
Dermatology recurring procedures	\$ 21,530	\$ 23,025
Dermatology procedures equipment	11,828	13,136
Total net revenues	<u>\$ 33,358</u>	<u>\$ 36,161</u>

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The following table summarizes the Company's expected future undiscounted fixed treatment code payments from international dermatology recurring procedures, the Company's only long-term arrangements (in thousands):

Years ending December 31:	
2024	\$ 1,319
2025	787
2026	569
2027	298
	<u>\$ 2,973</u>

Remaining performance obligations related to ASC 606 represent the aggregate transaction price allocated to performance obligations with an original contract term greater than one year, which are fully or partially unsatisfied at the end of the period. Remaining performance obligations include the potential obligation to perform under extended warranties and service contracts but exclude any dermatology procedures equipment accounted for as leases. As of December 31, 2023 and 2022, the aggregate amount of the transaction price allocated to remaining performance obligations was \$0.7 million and \$0.6 million, respectively, and the Company expects to recognize \$0.3 million and \$0.4 million, respectively, of the remaining performance obligations within one year and the remainder over one to three years. Contract assets primarily relate to the Company's rights to consideration for work completed in relation to its services performed but not billed at the reporting date. The contract assets are transferred to receivables when the rights become unconditional. Currently, the Company does not have any contract assets which have not transferred to a receivable.

Contract liabilities primarily relate to extended warranties and service contracts where the Company has received payments but has not yet satisfied the related performance obligations. The allocations of the transaction price are based on the price of standalone warranty contracts sold in the ordinary course of business. The advance consideration received from customers for the warranty services is a contract liability that is recognized ratably over the warranty period. As of December 31, 2023 and 2022, the \$0.3 million and \$0.4 million of short-term contract liabilities, respectively, is presented as deferred revenues and the \$0.4 million and \$0.2 million of long-term contract liabilities, respectively, is presented within deferred revenues and other liabilities on the consolidated balance sheets. For the years ended December 31, 2023 and 2022, the Company recognized \$0.4 million and \$0.9 million, respectively, as revenue from amounts classified as contract liabilities (i.e. deferred revenues) as of December 31, 2022 and 2021.

With respect to contract acquisition costs, the Company applies the practical expedient and expenses these costs immediately.

Engineering and Product Development

Engineering and product development costs associated with research, new product development and product redesign are expensed as incurred.

Advertising Costs

Advertising costs are expensed as incurred and included in selling and marketing expenses within the Company's consolidated statement of operations. The Company recognized advertising costs of \$0.5 million and \$1.6 million during the years ended December 31, 2023 and 2022, respectively.

Stock-Based Compensation

The Company measures share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the requisite service period of the awards.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the expected life of the options and stock price volatility. The Company accounts for forfeitures of stock option awards as they occur. The estimated fair value of restricted stock awards is equal to the Company's common stock price at the grant date. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in estimating the fair value of stock-option awards represent management's estimate and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards.

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Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities, as well as on net operating loss carryforwards, and are measured using enacted tax rates and laws that are expected to be in effect when the differences reverse. Any resulting net deferred tax assets are evaluated for recoverability and, accordingly, a valuation allowance is provided when it is not more likely than not that all or some portion of the deferred tax asset will be realized.

The Company recognizes the tax effects of uncertain tax positions only if the position is “more-likely-than-not” to be sustained were it to be challenged by a taxing authority. The assessment of the tax position is based solely on the technical merits of the position, without regard to the likelihood that the tax position may be challenged. If an uncertain tax position meets the “more-likely-than-not” threshold, the largest amount of tax benefit that is more than 50% likely to be recognized upon ultimate settlement with the taxing authority is recorded. The Company has no uncertain tax positions as of December 31, 2023. The Company includes interest and penalties related to income tax obligations within income tax expense. The Company’s tax years are still under open status from 2020 to present.

Net Loss Per Share

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities such as unvested restricted stock awards, stock options and warrants for common stock which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same as for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	December 31,	
	2023	2022
Stock options	7,728,721	4,474,714
Common stock warrants	800,000	373,626
Restricted stock units	22,654	278,004
	<u>8,551,375</u>	<u>5,126,344</u>

Accounting Pronouncements Recently Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, as amended subsequently by ASUs 2018-19, 2019-04, 2019-05, 2019-10, 2019-11 and 2020-03. The guidance in the ASUs requires that credit losses be reported using an expected losses model rather than the incurred losses model that was previously used. The standard also establishes additional disclosures related to credit risks. This standard was effective for fiscal years beginning after December 15, 2022. The adoption of this guidance on January 1, 2023 did not have a material effect on the consolidated financial statements.

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Recent Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivative and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's own Equity*. The pronouncement simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Specifically, the ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. In addition, the ASU removes certain settlement conditions that are required for equity contracts to qualify for it and simplifies the diluted earnings per share (EPS) calculations in certain areas. The guidance is effective for annual periods, including interim periods, beginning after December 15, 2023 and early adoption is permitted. The Company does not currently believe it will have a material effect on its consolidated financial statements, but it could in the future.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which will primarily require enhanced disclosures about significant segment expenses and information used to assess segment performance and enhanced disclosures in interim periods. The guidance in this ASU will be applied retrospectively and is effective for fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the effect this ASU will have on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in this ASU is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is currently evaluating the effect this ASU will have on its consolidated financial statements.

3. Asset Acquisition

In January 2022, the Company acquired certain assets related to the TheraClear devices from Theravant Corporation ("Theravant"). The TheraClear asset acquisition allows the Company to further develop, commercialize and market the TheraClear devices that are used for acne treatment, as well as advance the TheraClear technology into multiple other devices that can be used to treat a range of additional indications.

The Company made an upfront cash payment of \$0.5 million and issued to Theravant 358,367 shares of common stock with an aggregate value of \$0.5 million as of the closing date in connection with the TheraClear asset acquisition. During the fourth quarter of 2022, the Company also made a \$0.5 million milestone payment upon the launch of the TheraClear Acne Therapy System, one of the development-related targets. Theravant is eligible to receive up to \$3.0 million in future earnout payments upon the achievement of certain annual net revenue milestones (\$1.0 million of which is due upon the earlier of achieving a revenue target or July 2025), up to \$20.0 million in future royalty payments based upon a percentage of gross profit from future domestic sales ranging from 10-20%, 25% of gross profit from international sales over the subsequent four-year period, and up to \$0.5 million in future milestone payments upon the achievement of certain commercialization related targets. Through December 31, 2023, the Company has incurred \$0.1 million of royalty and gross profit payments based on gross profit from domestic and international sales.

The Company determined this transaction represented an asset acquisition as substantially all of the value was in the TheraClear technology intangible asset as defined by ASC 805, *Business Combinations*.

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The purchase price was allocated, on a relative fair value basis, to the technology intangible asset and acquired inventories as follows (in thousands):

Consideration:

Cash payment	\$	500
Common stock issued		500
Transaction costs		131
Contingent consideration		9,122
Total consideration	\$	<u>10,253</u>

Assets acquired:

Technology intangible asset	\$	10,182
Inventories		71
Total assets acquired	\$	<u>10,253</u>

The technology intangible asset is being amortized on a straight-line basis over a period of ten years, to be updated for subsequent changes in the contingent consideration that is allocated to its carrying value. The intangible asset was valued using the relief from royalty method. Significant assumptions used in the relief from royalty method include a 14.5% weighted average cost of capital and 15.0% of revenues for the royalty rate. The net book value of acquired inventories approximated its fair value. To calculate the fair value of the earnout using Monte Carlo simulations, Company projections were utilized to develop expected revenues and gross profits based on the risk inherent in the projections using the Geometric-Brownian motion for the earnout periods and related earnout payments. Significant assumptions used in the Geometric-Brownian motion analysis include projected revenues, projected gross profit, risk free rate of return of 1.6%, revenue volatility of 45.0%, and a cost of equity of 10.5%. Due to uncertainties associated with the development of a new product line and the use of estimates and assumptions to determine the fair value of the contingent consideration, the amount ultimately paid in connection with the earnout may differ from the estimated fair value at the acquisition date. A revaluation of the contingent consideration would only be required if there is a significant change to the underlying valuation assumptions. The contingent consideration will be adjusted when the contingency is resolved and the consideration is paid or becomes payable. Any difference between the cash payment and the amount accrued for contingent consideration will result in an adjustment to the technology intangible asset. Contingent consideration expected to be paid within the next year is classified as current on the consolidated balance sheet.

During 2023, the Company revised its projections of expected revenues and gross profits to be earned from TheraClear devices. The change in projections was considered significant enough to warrant a revaluation of the contingent consideration. To calculate the fair value of the earnout at December 31, 2023, using Monte Carlo simulations, Company projections were utilized to develop expected revenues and gross profits based on the risk inherent in the projections using the Geometric-Brownian motion for the earnout periods and related earnout payments. Significant assumptions used in the Geometric-Brownian motion analysis include projected revenues, projected gross profit, risk free rate of return of 3.8%, revenue volatility of 15.0%, and a cost of equity of 10.0%. The fair value of the contingent consideration as of December 31, 2023 was estimated to be \$1.2 million, which resulted in a reduction in contingent consideration of \$7.4 million with a corresponding adjustment to the carrying value of the technology intangible asset.

4. Fair Value Measurements

The carrying values of cash equivalents, restricted cash, accounts receivable, prepaid expenses and other current assets, and accounts payable on the Company's consolidated balance sheets approximated their fair values as of December 31, 2023 and 2022 due to their short-term nature. The carrying value of the Company's current Senior Term Facility approximated its fair value as of December 31, 2023 and 2022 due to its variable interest rate.

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5. Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2023	2022
Raw materials and work-in-process	\$ 2,192	\$ 2,966
Finished goods	481	129
	<u>\$ 2,673</u>	<u>\$ 3,095</u>

6. Property and Equipment, net

Property and equipment consist of the following (in thousands):

	December 31,	
	2023	2022
Lasers placed-in-service	\$ 32,095	\$ 28,790
Equipment, computer hardware and software	293	293
Furniture and fixtures	240	235
Leasehold improvements	203	136
Lasers-in-process	3,231	2,452
	<u>36,062</u>	<u>31,906</u>
Less: accumulated depreciation and amortization	<u>(24,284)</u>	<u>(21,956)</u>
	<u>\$ 11,778</u>	<u>\$ 9,950</u>

The Company recorded depreciation and amortization expense of \$2.9 million and \$2.4 million during the years ended December 31, 2023 and 2022, respectively.

7. Leases

The Company recognizes right-of-use assets (“ROU assets”) and operating lease liabilities when it obtains the right to control an asset under a leasing arrangement with an initial term greater than 12 months. The Company adopted the short-term accounting election for leases with a duration of less than one year. The Company leases its facilities and certain IT and office equipment under non-cancellable operating leases. All of the Company’s leasing arrangements are classified as operating leases with remaining lease terms ranging from one to three years, and one facility lease had a renewal option for two years. The renewal option was initially excluded from the determination of the lease term as it was not reasonably certain of exercise. In August 2022, the Company exercised the renewal option and amended the terms of the option, which has been accounted for as a lease modification. The ROU asset and operating lease liability were remeasured at the modification date, resulting in an increase to both balances of \$0.7 million during the year ended December 31, 2022. There were no lease modifications during the year ended December 31, 2023.

Operating lease costs were \$0.4 million for each of the years ended December 31, 2023 and 2022. Cash paid for amounts included in the measurement of operating lease liabilities was \$0.4 million for each of the years ended December 31, 2023 and 2022. As of December 31, 2023 and 2022, the weighted average incremental borrowing rate was 8.60% and 8.76%, respectively, and the weighted average remaining lease term was 2.0 years and 2.8 years, respectively.

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The following table summarizes the Company's operating lease maturities as of December 31, 2023 (in thousands):

Years ending December 31:	
2024	\$ 386
2025	195
2026	55
Total remaining lease payments	636
Less: imputed interest	(47)
Total lease liabilities	<u>\$ 589</u>

With respect to lease and non-lease components, the Company adopted the practical expedient to account for the lessee arrangement as a single lease component.

8. Intangible Assets and Goodwill

Intangible assets consist of the following (in thousands):

	Balance	Accumulated Amortization	Net Book Value
December 31, 2023			
Core technology	\$ 5,700	\$ (4,845)	\$ 855
Product technology	4,808	(3,866)	942
Customer relationships	6,900	(5,865)	1,035
Tradenames	1,500	(1,275)	225
Pharos customer lists	5,314	(1,052)	4,262
	<u>\$ 24,222</u>	<u>\$ (16,903)</u>	<u>\$ 7,319</u>
December 31, 2022			
Core technology	\$ 5,700	\$ (4,275)	\$ 1,425
Product technology	12,182	(3,018)	9,164
Customer relationships	6,900	(5,175)	1,725
Tradenames	1,500	(1,125)	375
Pharos customer lists	5,314	(609)	4,705
	<u>\$ 31,596</u>	<u>\$ (14,202)</u>	<u>\$ 17,394</u>

The Company recorded amortization expense of \$2.7 million and \$2.9 million during the years ended December 31, 2023 and 2022, respectively.

During the year ended December 31, 2023 the Company recognized an adjustment of \$7.4 million to the carrying value of product technology as a result of the revaluation of contingent consideration related to the TheraClear asset acquisition (Note 3).

The following table summarizes the estimated future amortization expense for the above intangible assets for the next five years (in thousands):

Years ending December 31:	
2024	1,971
2025	1,266
2026	561
2027	561
2028	561

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Goodwill consists of the following (in thousands):

	December 31,	
	2023	2022
Dermatology recurring procedures segment	\$ 5,674	\$ 7,958
Dermatology procedures equipment segment	845	845
	<u>\$ 6,519</u>	<u>\$ 8,803</u>

During the year ended December 31, 2023, the Company recognized a goodwill impairment charge of \$2.3 million related to the dermatology recurring procedures segment primarily driven by a decline in projected cash flows, including revenues and profitability (see Note 2).

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2023	2022
Warranty obligations	\$ 180	\$ 136
Compensation and related benefits	1,679	1,997
State sales, use and other taxes	4,316	3,986
Professional fees and other	131	436
	<u>\$ 6,306</u>	<u>\$ 6,555</u>

10. Long-Term Debt

On September 30, 2021, the Company entered into a credit and security agreement with MidCap Financial Trust (“MidCap”), also acting as the administrative agent, and the lenders identified therein. The original terms provided for an \$8.0 million senior term loan. Borrowings under the senior term loan originally bore interest at LIBOR (with a LIBOR floor rate of 0.50%) plus 7.50% per year and were scheduled to mature on September 1, 2026, unless terminated earlier. The Company was obligated to make monthly interest-only payments through September 30, 2024. The credit and security agreement was amended on January 10, 2022 to provide MidCap’s consent to the TheraClear asset acquisition (Note 3). On September 6, 2022, the Company amended the facility to transition, upon the cessation of LIBOR, to one-month Secured Overnight Financing Rate (“SOFR”), or such other applicable period, plus 0.10%, with a floor of 0.50%.

On June 30, 2023, the Company entered into (a) Amendment No. 3 to the credit and security agreement (the “Third Amendment”); (b) the Amended and Restated Warrant Agreement (the “A&R Warrant”) with MidCap Funding XXVII Trust (together with any registered holder from time to time or any holder of the shares issuable or issued upon the exercise or conversion of the warrant, the “Warranholder”), which amended and restated the warrant agreement to purchase shares of the common stock of the Company, dated as of September 30, 2021 (the “Prior Warrant”), with the Warranholder; (c) the Amended and Restated Registration Rights Agreement (the “A&R Registration Rights Agreement”) with the Warranholder, which amended and restated the registration rights agreement, dated as of September 30, 2021, with the Warranholder; and (d) a letter agreement (the “Fee Letter Agreement”) with MidCap, as agent.

On February 20, 2024, the Company entered into (a) Amendment No. 4 to the credit and security agreement (the “Fourth Amendment”) which amended the credit and security agreement (as amended by the Third and Fourth Amendments, the “Senior Term Facility”), and (b) a second amended and restated letter agreement (“Amended Fee Letter Agreement”) with MidCap, as agent.

On March 27, 2024, the Company entered into Amendment No. 5 to the credit and security agreement, which clarified certain provisions related to the maintenance of cash collateral accounts.

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The Senior Term Facility provides for a senior secured term loan facility of \$20.0 million, of which \$8.0 million was drawn by the Company on September 30, 2021 (“Credit Facility #1”), \$7.0 million was drawn by the Company on June 30, 2023 (“Credit Facility #2”), and an additional \$5.0 million tranche (“Credit Facility #3”) is available to be drawn by the Company if its Dermatology Recurring Procedures Revenue (as defined in the Senior Term Facility) for the preceding 12 calendar months (ending on the last day of the calendar month for which a compliance certificate is delivered) is greater than or equal to \$30.0 million (such condition, the “Applicable Funding Condition”). Credit Facility #3 can be drawn beginning on the later of the satisfaction of the Applicable Funding Condition and January 1, 2024, with such commitment terminating on the earlier to occur of December 31, 2024 and the delivery of a written notice by MidCap to the Company terminating the applicable commitments following an Event of Default (as defined in the Senior Term Facility) that has not been waived or cured at the time such notice is delivered. All borrowings are secured by substantially all of the Company’s assets.

Borrowings under the Senior Term Facility bear interest at a rate per annum equal to the sum of (a) the greater of (i) the sum of (A) 30-day forward-looking term rate of one month SOFR, as published by CME Group Benchmark Administration Limited, from time to time, plus (B) 0.10%, and (ii) the applicable floor rate of 3.50%, with such sum reset monthly, and (b) 7.50%. The effective interest rate of the Senior Term Facility as of December 31, 2023 and 2022 was 13.68% and 11.72%, respectively. The Company is obligated to make interest-only payments (payable monthly in arrears) through June 1, 2026. Commencing on July 1, 2026 and continuing for the remaining 24 months of the facility, the Company will be required to make monthly interest payments and monthly principal payments based on a straight-line amortization schedule set forth in the Senior Term Facility, subject to certain adjustments as described in the Senior Term Facility. The final maturity date under the Senior Term Facility is June 1, 2028, unless earlier terminated. The Senior Term Facility requires the Company to dedicate 100% of certain insurance proceeds to the prepayment of the outstanding term loan, subject to certain exceptions and net of certain expenses and repayments.

The Company may voluntarily prepay the outstanding term loan under the Senior Term Facility, with such prepayment in an amount of at least \$5.0 million, at any time upon 30 days’ written notice. Upon prepayment, the Company will be required to pay a prepayment fee equal to (i) 4.00% of the outstanding principal prepaid or required to be prepaid (whichever is greater), if the prepayment is made within 12 months of February 20, 2024, (ii) 3.00% of the outstanding principal prepaid or required to be prepaid (whichever is greater), if the prepayment is made between 12 months and 24 months after February 20, 2024, (iii) 2.00% of the outstanding principal prepaid or required to be prepaid (whichever is greater), if the prepayment is made between 24 months and 36 months after February 20, 2024, or (iv) 1.00% of the outstanding principal prepaid or required to be prepaid (whichever is greater), if the prepayment is made after 36 months after February 20, 2024 and prior to the maturity date.

The Senior Term Facility contains certain customary representations and warranties, affirmative covenants and conditions, as well as various negative covenants. Further, the Senior Term Facility contains (a) a quarterly financial covenant that requires the Company to not have less than \$29.0 million of net revenue (raised to \$33.0 million by December 31, 2026 and, for periods ending after December 31, 2026, such net revenue as determined in good faith by MidCap, which shall not be less than the applicable minimum net revenue amount for the immediately preceding period and \$33.0 million) for the trailing 12-month period as of March 31, 2024, and (b) a minimum of unrestricted cash (as defined in the Senior Term Facility), at all times, of not less than \$3.0 million. Prior to the execution of the Fourth Amendment, the minimum net revenue threshold was \$36.0 million for the trailing 12-month period as of December 31, 2023, which the Company did not meet. Through the Fourth Amendment, MidCap granted a limited waiver of this event of default that occurred as of December 31, 2023 and of any right MidCap had to exercise its rights against the Company as a result. At December 31, 2023, the Company was in compliance with all other financial covenants within the Senior Term Facility.

Upon the occurrence and during the continuance of an event of default, MidCap may, and at the direction of a requisite percentage of the lenders must, (i) suspend or terminate the term loan commitment and MidCap and the other lenders’ obligations with respect thereto, and (ii) by notice to the Company, declare all or any portion of the obligations under the Senior Term Facility to be immediately due and payable. In addition to MidCap’s other rights and available remedies, but subject to applicable cure periods, upon the occurrence and during the continuance of an event of default, MidCap may, and at the direction of a requisite percentage of the lenders must, terminate the Senior Term Facility. Given that the Fourth Amendment granted a limited waiver as described above, as of December 31, 2023, the Company believed that events or conditions having a material adverse effect, giving rise to an acceleration of any amounts outstanding under the Senior Term Facility, had not occurred and was remote.

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Pursuant to the Amended Fee Letter Agreement, the Company agreed to pay MidCap, as administrative agent, the following fees: (a) an origination fee on June 30, 2023 in an amount equal to (i) the Credit Extensions (as defined in the Senior Term Facility) in respect of Credit Facility #2, multiplied by (ii) 0.50%; (b) on the maturity date of the Senior Term Facility or any earlier date on which the obligations thereunder become due and payable in full or are otherwise paid in full (such date, the “Full Exit Fee Payment Date”), the Company shall pay an exit fee equal to (i) 4.00% of the total aggregate principal amount of Credit Extensions (as defined in the Senior Term Facility) made pursuant to the Senior Term Facility (regardless of any repayment or prepayment thereof) as of the Full Exit Fee Payment Date (such aggregate amount, the “Exit Fee Base Amount”), less (ii) any Partial Exit Fee (as defined below) previously paid; (c) on the date of any voluntary or mandatory partial prepayment of the borrowings under the Senior Term Facility (or on the date such mandatory prepayment becomes due and payable) (each such date, a “Partial Exit Fee Payment Date”), the Company shall pay an exit fee equal to 4.00% of the principal amount of the credit facilities paid or prepaid (or required to be paid in the case of a mandatory prepayment) as of the Partial Exit Fee Payment Date (such amount, the “Partial Exit Fee”); and (d) an origination fee payable contemporaneously with funding Credit Facility #3 in an amount equal to (i) the Credit Extensions (as defined in the Senior Term Facility) in respect of Credit Facility #3, multiplied by (ii) 0.50%.

The Prior Warrant allowed the Warrantholder, an affiliate of the lender, to purchase 373,626 shares of the Company’s common stock at an exercise price equal to \$1.82 per share for a 10-year period ending September 30, 2031. Pursuant to, and in accordance with, the terms and conditions of the A&R Warrant, which amended and restated the Prior Warrant, the Warrantholder can purchase 800,000 shares of the Company’s common stock at an exercise price equal to \$0.88 per share for a 10-year period ending on June 30, 2033. Pursuant to the A&R Registration Rights Agreement, the Company registered the shares underlying the A&R Warrant effective August 18, 2023. The amendment of the warrant resulted in an increase in the fair value of the warrant, which has been accounted for as a lender fee.

The Third Amendment has been accounted for as a debt extinguishment, as the new loan is considered substantially different from the original loan. The Company recorded a loss on debt extinguishment of \$0.9 million for the year ended December 31, 2023, which includes unamortized debt discount on the original loan of \$0.4 million, an increase in the fair value of the warrant of \$0.4 million and lender fees of \$0.1 million. In connection with the Third Amendment, the Company recorded the \$0.5 million exit fee (equal to 3.00% of the aggregate principal amount of Credit Extensions #1 and #2 prior to execution of the Fourth Amendment) as both a debt discount and an increase to the principal amount of the debt. The debt discount, which also includes third party costs incurred in connection with the Third Amendment of \$13 thousand, is being recognized as interest expense over the term of the Senior Term Facility using the effective-interest method. The unamortized debt discount was \$0.4 million and \$0.5 million as of December 31, 2023 and 2022, respectively. The Company recognized interest expense of \$1.6 million during the year ended December 31, 2023, of which \$0.1 million was related to the amortization of the debt discount. The Company recognized interest expense of \$0.9 million during the year ended December 31, 2022, of which \$0.2 million was related to the amortization of the debt discount.

Future minimum principal payments at December 31, 2023 are as follows (in thousands):

Years ending December 31:

2026	\$	3,750
2027		7,500
2028		3,750
		15,000
Exit fee		450
		15,450
Less: unamortized debt discount		(406)
Long-term debt, net	\$	15,044

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11. Commitments and Contingencies

Legal Matters

In the ordinary course of business, the Company is routinely a defendant in or party to pending and threatened legal actions and proceedings, including actions brought on behalf of various classes of claimants. These actions and proceedings are generally based on alleged violations of employment, contract, and other laws. In some of these actions and proceedings, claims for substantial monetary damages are asserted against the Company. In the ordinary course of business, the Company is also subject to regulatory and governmental examinations, information gathering requests, inquiries, investigations, and threatened legal actions and proceedings. In connection with formal and informal inquiries by federal, state, local and foreign agencies, the Company receives numerous requests, subpoenas and orders for documents, testimony, and information in connection with various aspects of its activities.

On April 1, 2022, a proposed representative class action under California's Private Attorneys General Act ("PAGA") was filed in Superior Court of California, County of San Diego against the Company and an employment agency which provided the Company with temporary employees. The complaint alleges various violations of the California Labor Code, including California's wage and hour laws, relating to current and former non-exempt employees of the Company. The complaint seeks class status and payments for allegedly unpaid compensation and attorney's fees. In a related matter, the attorneys in this matter and the proposed class representative, in a letter dated March 12, 2022, to the California Labor & Workforce Development Agency made nearly identical claims seeking the right to pursue a PAGA action against the Company and the employment agency. On or about May 16, 2022, the plaintiff filed a First Amended Complaint adding a PAGA claim to the action. On or about June 2, 2022, the plaintiff filed an Application to Dismiss Class and Individual Claim without prejudice, in an attempt to pursue a PAGA only complaint. On or about June 30, 2022, the parties entered into a stipulation to allow the plaintiff to file a Second Amended Complaint to clarify the PAGA claim and to stay the pending action to allow an attempt at resolution through mediation. The mediation was held on February 23, 2023, and the matter was settled on terms agreeable to the Company. The settlement, which requires the Company to pay \$0.1 million, was subject to the right of individual class members to opt out of the settlement and proceed on their own. No individual has requested to opt out of the settlement. As of December 31, 2023, \$0.1 million has been accrued for this matter.

Sales and Use Tax Matters

The Company records state sales tax collected and remitted for its customers on dermatology procedures equipment sales on a net basis, excluded from revenue. The Company's sales tax expense that is not presently being collected and remitted for the recurring revenue business is recorded in general and administrative expenses within the consolidated statements of operations.

The Company believes its state sales and use tax accruals have been properly recognized such that, if the Company's arrangements with customers are deemed more likely than not that the Company would not be exempt from sales tax in a particular state, the basis for measurement of the state sales and use tax is calculated in accordance with ASC 405, *Liabilities*, as a transaction tax. If and when the Company is successful in defending itself or in settling the sales tax obligation for a lesser amount, the reversal of this liability is to be recorded in the period the settlement is reached. However, the precise scope, timing, and time period at issue, as well as the final outcome of any audit and actual settlement, remains uncertain.

In the ordinary course of business, the Company is, from time to time, subject to audits performed by state taxing authorities. These actions and proceedings are generally based on the position that the arrangements entered into by the Company are subject to sales and use tax rather than exempt from tax under applicable law. The states of New York and California have assessed the Company an aggregate of \$3.9 million including penalties and interest. The audits cover the period from March 2014 through November 2022. The Company received notification that an administrative state judge in New York issued an opinion finding in favor of the Company that the sale of XTRAC treatment codes was not taxable as sales tax with respect to that state's first assessment. This ruling covers \$1.4 million of the total \$3.9 million of assessments. The relevant taxing authority filed an appeal of the administrative law judge's finding and, following the submission of legal briefs by both sides and oral argument held in January 2022, on May 6, 2022, the Company received a written decision from the Tribunal overturning the favorable sales tax determination of the administrative law judge. The Company appealed the Tribunal's decision to the Appellate Division, and posted the required appellate bond in the form of cash collateral. Oral argument was held by the Appellate Division on January 18, 2024.

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On March 8, 2024, the Company received a decision from the Appellate Division ruling against it in the matter of its sales tax appeal, affirming the Tribunal's ruling that the Company's sale of XTRAC treatment codes is subject to sales tax. The Appellate Division concluded that, through the usage arrangements, the Company's customers had possession of the laser devices and had a license and ability to use the laser devices. The Appellate Division also agreed with the Tribunal that the primary function analysis was not applicable in this matter. The Company will be filing a motion to appeal the Appellate Division's decision.

The Company is also in the administrative process of appeal with respect to the remaining \$2.5 million of assessments. If there is a determination that the true object of the Company's recurring revenue model is not exempt from sales taxes and is not a prescription medicine, or the Company does not have other defenses where the Company prevails, the Company may be subject to sales taxes in those particular states for previous years and in the future, plus potential interest and penalties.

The precise scope, timing and time periods at issue, as well as the final outcomes of the investigations and judicial proceedings, remain uncertain. Accordingly, the Company's estimate may change from time to time, and actual losses could vary.

Employee 401(k) Savings Plan

The Company sponsors a 401(k) defined contribution retirement savings plan that covers all eligible employees who have met the minimum age and service requirements. Under the plan, eligible employees may contribute a portion of their annual compensation into the plan up to IRS annual limits. The Company has elected to make matching contributions to the plan based on a percentage of the employee's contribution. For the years ended December 31, 2023 and 2022, the Company's contributions to the plan were \$0.4 million and \$0.3 million, respectively.

Milestone Payments

In January 2022, the Company entered into a Development Agreement (the "Development Agreement") with Theravant. Under the Development Agreement, the Company will reimburse Theravant for costs incurred in further developing certain TheraClear technology and other healthcare products and methods for the medical aesthetic marketplace. In connection with the development of three devices, Theravant is eligible to receive \$0.5 million upon FDA clearance for each device and \$0.5 million upon achievement of certain net revenue targets for each device, aggregating to \$3.0 million of potential future milestone payments under the Development Agreement. The Development Agreement has a three-year term, unless terminated sooner by either party, and is being accounted for separately from the TheraClear asset acquisition discussed in Note 3.

12. Stockholders' Equity

Preferred Stock

The Company is authorized to issue preferred stock with such designation, rights and preferences as may be determined from time to time by the Company's Board of Directors. Other than the limitations on conversions to keep each such holder's beneficial ownership below 9.99%, the terms of the Series C convertible preferred stock generally bestow the same rights to each holder as such holder would receive if they were common stock shareholders and are not redeemable by the holders, except that the Series C convertible preferred stock shares do not have voting rights. Each share of Series C convertible preferred stock has a stated value of \$1,000 and is convertible into shares of common stock at a conversion price equal to \$2.69. No preferred shares were outstanding as of December 31, 2023 and 2022.

Common Stock

The Company issued 337,874 shares upon the vesting of restricted stock during the year ended December 31, 2023.

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On June 26, 2023, the Company had received written notification from the Nasdaq Stock Market (“Nasdaq”) that the closing bid price of its common stock had been below the minimum \$1.00 per share for the previous 30 consecutive business days and that the Company, therefore, was not in compliance with the requirements for continued listing on the Nasdaq Capital Market. On December 27, 2023, the Company received written notice from Nasdaq that it had been granted a 180-day extension, or until June 24, 2024, to regain compliance with Nasdaq’s minimum bid price rule.

The Company issued 358,367 shares to Theravant as consideration for the TheraClear asset acquisition (Note 3) during the year ended December 31, 2022.

In October 2021, the Company entered into an equity distribution agreement under which the Company may sell up to \$11.0 million of its shares of common stock in registered “at-the-market” offerings. The shares will be offered at prevailing market prices, and the Company will pay commissions of up to 3.0% of the gross proceeds from the sale of shares sold through the Company’s agent, which may act as an agent and/or principal. The Company has no obligation to sell any shares under this agreement and may, at any time, suspend solicitations under this agreement. No shares of the Company’s common stock have been sold under this distribution agreement during fiscal 2023 or 2022.

Common Stock Warrants

In September 2021 and in connection with entering into the Company’s Senior Term Facility (Note 10), the Company issued a warrant to purchase 373,626 shares of the Company’s common stock at an initial exercise price of \$1.82 per share. The warrant was amended in June 2023 in connection with the execution of the Third Amendment to the Senior Term Facility. The amended warrant is to purchase 800,000 shares of the Company’s common stock at an exercise price equal to \$0.88 per share. The warrant is equity classified and is exercisable at any time on or prior to the tenth anniversary of its amendment date. As of December 31, 2023, the warrant remains outstanding in its entirety.

13. Stock-Based Compensation

The Company’s 2016 Omnibus Incentive Stock Plan (“2016 Plan”), as amended, has reserved up to 7,832,651 shares of common stock for future issuance. As of December 31, 2023, there were 1,329,375 shares of common stock remaining available for issuance for awards under the 2016 Plan.

The Company measures share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the requisite service period of the awards. The Company recorded share-based compensation expense (for all awards and modifications, if any) in the accompanying consolidated statements of operations as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Selling and marketing	\$ 79	\$ 203
General and administrative	1,224	1,263
	<u>\$ 1,303</u>	<u>\$ 1,466</u>

On April 3, 2023 and March 30, 2022, the Company granted 150,000 and 160,000 stock-based options, respectively, to its former Chief Executive Officer. The vesting of these awards was contingent upon meeting one or more financial goals (a performance condition) or a common stock share price (a market condition). The fair value of stock-based awards is determined at the date of grant. Stock-based compensation expense is recorded ratably for market condition awards during the requisite service period and is not reversed, except for forfeitures, at the vesting date regardless of whether the market condition is met. Stock-based compensation expense for performance condition awards is re-evaluated at each reporting period based on the probability of the achievement of the goal. The market condition was not met for the 2022 awards and 60,000 of the stock-based options were forfeited during 2022. The 150,000 stock-based options awarded in 2023 were forfeited by December 31, 2023 due to the Chief Executive Officer’s separation and failure to achieve the vesting conditions.

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Also in connection with the separation of the Company's Chief Executive Officer in October 2023, the vesting of 272,098 unvested options to purchase shares of common stock was accelerated. As this acceleration of vesting occurred in accordance with the terms of the original option agreement, it is not considered a modification for accounting purposes. The Company recognized \$0.3 million of share-based compensation expense in connection with the accelerated vesting.

Stock Options

The following table summarizes stock option activity for the years ended December 31, 2023 and 2022:

	Number of Shares Under Option Plan	Weighted- Average Exercise Price per Option	Weighted- Average Remaining Contractual Term (in years)
Outstanding at January 1, 2022	3,938,613	\$ 1.90	
Granted	1,000,000	1.41	
Exercised	(15,000)	1.29	
Forfeited and expired	(448,899)	2.63	
Outstanding at December 31, 2022	4,474,714	\$ 1.72	8.02
Granted	4,545,069	0.63	
Forfeited and expired	(1,291,062)	1.56	
Outstanding at December 31, 2023	7,728,721	1.11	6.70
Exercisable at December 31, 2023	1,256,062	\$ 1.75	2.09

The weighted-average grant date fair value of options granted was \$0.44 and \$1.06 per share during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the total unrecognized compensation expense related to unvested stock option awards was \$2.1 million, which the Company expects to recognize over a weighted-average period of approximately 3.1 years. The aggregate intrinsic value of options outstanding at December 31, 2023 was \$0.1 million. There was no aggregate intrinsic value of options exercisable at December 31, 2023 and no options were exercised during the year ended December 31, 2023. There was no aggregate intrinsic value of options outstanding and options exercisable at December 31, 2022 or of options that were exercised during the year ended December 31, 2022.

The fair value of options is estimated using the Black-Scholes option pricing model which takes into account inputs such as the exercise price, the value of the underlying common stock at the grant date, expected term, expected volatility, risk free interest rate and dividend yield. The fair value of each grant of options during the year ended December 31, 2023 and 2022 was determined using the methods and assumptions discussed below.

- The expected term of employee options is based on the observed and expected time to full-vesting, forfeiture and exercise. Groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. Options expire up to a maximum of ten years from the date of grant.
- The expected volatility is based on historical volatility of the Company's common stock.
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- The expected dividend yield is none because the Company has not historically paid and does not expect for the foreseeable future to pay a dividend on its shares of common stock.

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For the years ended December 31, 2023 and 2022, the grant date fair value of all option grants was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	Year Ended December 31,	
	2023	2022
Expected term (in years)	7.49	6.10
Expected volatility	74.58%	89.57%
Risk-free rate	4.38%	2.51%
Dividend rate	0.00%	0.00%

Restricted Stock Units

Restricted stock units have been issued to certain board members. Activity in restricted stock units is summarized in the following table:

	Number of Units	Weighted- Average Grant Date Fair Value
Unvested at January 1, 2022	90,540	\$ 1.45
Granted	187,464	0.96
Vested	(158,407)	1.26
Unvested at December 31, 2022	119,597	\$ 0.93
Granted	179,613	1.03
Vested	(179,467)	0.96
Forfeited and expired	(97,089)	1.03
Unvested at December 31, 2023	<u>22,654</u>	<u>\$ 1.03</u>

As of December 31, 2023, the total unrecognized compensation expense related to unvested restricted stock units was \$18 thousand, which the Company expects to recognize over a weighted-average period of approximately 0.5 years.

14. Income Taxes

Income tax expense consists of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Current:		
Federal	\$ —	\$ —
State	28	23
	<u>28</u>	<u>23</u>
Deferred:		
Federal	(68)	23
State	(52)	17
	<u>(120)</u>	<u>40</u>
(Benefit from) / provision for income taxes	<u>\$ (92)</u>	<u>\$ 63</u>

Deferred tax assets and liabilities are determined based on the differences between the consolidated financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which differences are expected to reverse.

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Significant components of the Company's deferred tax liability for federal income taxes consisted of the following (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	\$ 46,718	\$ 45,077
Intangible assets	2,138	1,697
Inventories	71	57
Reserves and accrued expenses	1,381	1,431
Stock-based compensation	180	548
Operating lease liabilities	145	240
Interest expense limitation carryover	552	208
Property and equipment	—	1,111
Gross deferred tax assets	<u>51,185</u>	<u>50,369</u>
Less: valuation allowance	<u>(50,139)</u>	<u>(49,005)</u>
	<u>1,046</u>	<u>1,364</u>
Deferred tax liabilities:		
Property and equipment	(412)	—
Operating lease right-of-use assets	(154)	(242)
Goodwill	(666)	(1,095)
481(a) adjustment	—	(333)
	<u>(1,232)</u>	<u>(1,670)</u>
Net deferred tax liability	<u>\$ (186)</u>	<u>\$ (306)</u>

In assessing the need for a valuation allowance, management must determine that there will be sufficient taxable income to allow for the realization of deferred tax assets. Based upon historical and anticipated future losses, management has determined that the deferred tax assets do not meet the more likely than not threshold for realizability. Accordingly, a nearly full valuation allowance has been recorded against the Company's deferred tax assets as of December 31, 2023. The valuation allowance increased by \$1.1 million during the year ended December 31, 2023. The Company does not have unrecognized tax benefits as of December 31, 2023 or 2022. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

The Company had net operating loss ("NOL") carryforwards for federal and state income tax purposes as follows (in thousands):

	December 31,	
	2023	2022
Federal	\$ 205,212	\$ 198,144
State	\$ 63,566	\$ 60,784

The NOL carryforwards generated prior to 2018 began to expire for federal income tax purposes and begin expiring in 2030 for state income tax purposes. Federal and many state NOLs generated in 2018 and into the future now have an indefinite life.

The NOL carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. To date, the Company has not performed an analysis to determine whether or not ownership changes have occurred since inception.

STRATA Skin Sciences, Inc. and Subsidiary
Notes to Consolidated Financial Statements

A reconciliation of income tax expense at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements is as follows:

	Year Ended December 31,	
	2023	2022
Federal tax expense at statutory rate	21.00%	21.00%
State tax, net of federal benefit	0.18%	(0.58)%
Permanent differences	(1.89)%	(2.23)%
Other difference and true ups	(8.07)%	(11.20)%
Change in valuation allowance	(10.38)%	(8.14)%
Effective income tax rate	<u>0.84%</u>	<u>(1.15)%</u>

On August 16, 2022, the U.S. enacted the Inflation Reduction Act of 2022 (“IRA”). The IRA contains certain tax measures, including a corporate alternative minimum tax of 15% on some large corporations and an excise tax of 1% on corporate stock repurchases. The provisions of the IRA did not have an impact on the Company’s consolidated financial statements for the year ended December 31, 2023, as the Company currently does not qualify as a large corporation for the 15% alternative minimum tax and there were no stock repurchases during 2023. The Company will monitor its operations for changes that could impact the applicability of the IRA provisions in future tax years.

15. Business and Geographical Reporting Segments

The Company organized its business into two operating segments to better align its organization based upon the Company’s management structure, products and services offered, markets served and types of customers, as follows. The Dermatology Recurring Procedures segment derives its revenues from the usage of its equipment by dermatologists to perform XTRAC procedures. The Dermatology Procedures Equipment segment generates revenues from the sale of equipment, such as lasers and lamp products. Management reviews financial information presented on an operating segment basis for the purposes of making certain operating decisions and assessing financial performance.

Unallocated operating expenses include costs that are not specific to a particular segment but are general to the group; included are expenses incurred for administrative and accounting staff, general liability and other insurance, professional fees and other similar corporate expenses. Interest and other financing income (expense) is also not allocated to the operating segments.

STRATA Skin Sciences, Inc. and Subsidiary
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The following tables reflect results of operations from our business segments for the periods indicated below (in thousands, except gross profit %):

Year Ended December 31, 2023	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Total
Revenues	\$ 21,530	\$ 11,828	\$ 33,358
Cost of revenues	8,729	6,168	14,897
Gross profit	12,801	5,660	18,461
Gross profit %	59.5%	47.9%	55.3%
Allocated expenses:			
Engineering and product development	1,011	306	1,317
Selling and marketing	11,169	1,787	12,956
Impairment of goodwill	2,284	—	2,284
Unallocated expenses	—	—	10,508
	<u>14,464</u>	<u>2,093</u>	<u>27,065</u>
(Loss) income from operations	(1,663)	3,567	(8,604)
Interest expense	—	—	(1,640)
Interest income	—	—	231
Loss on debt extinguishment	—	—	(909)
(Loss) income before benefit from / (provision for) income taxes	<u>\$ (1,663)</u>	<u>\$ 3,567</u>	<u>\$ (10,922)</u>

Year Ended December 31, 2022	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Total
Revenues	\$ 23,025	\$ 13,136	\$ 36,161
Cost of revenues	8,371	6,022	14,393
Gross profit	14,654	7,114	21,768
Gross profit %	63.6%	54.2%	60.2%
Allocated expenses:			
Engineering and product development	672	357	1,029
Selling and marketing	13,503	1,798	15,301
Unallocated expenses	—	—	10,087
	<u>14,175</u>	<u>2,155</u>	<u>26,417</u>
Income (loss) from operations	479	4,959	(4,649)
Interest expense	—	—	(926)
Interest income	—	—	89
Income (loss) before benefit from / (provision for) income taxes	<u>\$ 479</u>	<u>\$ 4,959</u>	<u>\$ (5,486)</u>

For the years ended December 31, 2023 and 2022, depreciation and amortization by reportable segment were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Dermatology recurring procedures	\$ 4,793	\$ 4,421
Dermatology procedures equipment	746	857
Unallocated expenses	14	15
Total	<u>\$ 5,553</u>	<u>\$ 5,293</u>

STRATA Skin Sciences, Inc. and Subsidiary
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The following tables present the Company's revenue disaggregated by geographical region for the years ended December 31, 2023 and 2022 (in thousands). Domestic refers to revenue from customers based in the United States, and foreign revenue is derived from the Company's distributors primarily in Asia.

Year Ended December 31, 2023	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Total
Domestic	\$ 20,215	\$ 2,813	\$ 23,028
China	—	3,340	3,340
Korea	673	2,055	2,728
Other foreign	642	3,620	4,262
Total	<u>\$ 21,530</u>	<u>\$ 11,828</u>	<u>\$ 33,358</u>

Year Ended December 31, 2022	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Total
Domestic	\$ 21,585	\$ 2,396	\$ 23,981
China	195	4,556	4,751
Korea	888	2,828	3,716
Other foreign	357	3,356	3,713
Total	<u>\$ 23,025</u>	<u>\$ 13,136</u>	<u>\$ 36,161</u>

As of December 31, 2023 and 2022, total assets by reportable segment were as follows (in thousands):

	December 31,	
	2023	2022
Dermatology recurring procedures	\$ 28,137	\$ 37,230
Dermatology procedures equipment	5,507	7,890
Other unallocated assets	8,372	7,152
Total	<u>\$ 42,016</u>	<u>\$ 52,272</u>

Long-lived assets of \$0.8 million and \$0.6 million were located in international markets, primarily Korea and Japan, as of December 31, 2023 and 2022, respectively, with the remainder located in domestic markets.

16. Subsequent Events

On February 20, 2024, the Company amended its credit and security agreement and fee letter agreement with MidCap. On March 27, 2024, the Company further amended its credit and security agreement with MidCap. See Note 10 for details.

DESCRIPTION OF OUR COMMON STOCK**General**

The following description of the material provisions of our capital stock (which includes a description of securities we may offer pursuant to the registration statement of which this prospectus, as the same may be supplemented, forms a part) does not purport to be complete and is based on and qualified by our Certificate of Incorporation, as amended and restated (the "Charter"), our Bylaws, and our Warrant Agreement to Purchase Shares of the Common Stock of STRATA Skin Sciences, Inc., dated as of June 30, 2023, between us and MidCap Funding XXVII Trust ("Warrant Agreement"), each of which is incorporated by reference in the registration statement of which this prospectus is a part. The summary below is also qualified by reference to provisions of the Delaware General Corporation Law ("DGCL"). The Warrant Agreement supersedes and replaces a previous warrant agreement between the Company and Midcap, dated September 30, 2021.

Our authorized capital stock consists of 160,000,000 shares, consisting of 150,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.10 par value per share. As of December 31, 2023, our outstanding capital stock consists of 34,723,046 shares of common stock, and no shares of preferred stock. These figures do not include (i) securities that may be issued upon exercise or vesting of our outstanding derivative securities including our options to purchase shares of common stock and restricted stock units under our equity incentive plans and a stock purchase warrant, and (ii) 358,367 shares of common stock issued to Theravant Corporation, a Delaware corporation ("Theravant"), pursuant to the terms and conditions of an Asset Purchase Agreement entered into between us, Theravant and certain other parties thereto.

We, directly or through agents, dealers or underwriters designated from time to time, may offer, issue and sell, together or separately, up to \$25,000,000 in the aggregate of:

- common stock;
- preferred stock;
- secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities;
- warrants to purchase our securities;
- rights to purchase our securities; or
- units comprised of, or other combinations of, the foregoing securities.

We may issue the debt securities as exchangeable for or convertible into shares of common stock, preferred stock or other securities. The preferred stock may also be exchangeable for and/or convertible into shares of common stock, another series of preferred stock or other securities. The debt securities, the preferred stock, the common stock and the warrants are collectively referred to in this prospectus as the "securities." When a particular series of securities is offered, a supplement to this prospectus will be delivered with this prospectus, which will set forth the terms of the offering and sale of the offered securities.

Common Stock

As of December 31, 2023, there were 34,723,046 shares of common stock issued and outstanding. The outstanding shares of common stock are duly authorized, validly issued, fully paid and non-assessable.

Voting Power

Except as otherwise required by law or as provided in any certificate of designation for any series of Preferred Stock, the holders of common stock possess all the voting power for the election of our directors and all other matters requiring stockholder action. Holders of common stock are entitled to one vote per share held of record on matters to be voted on by stockholders.

Dividends

Holders of common stock will be entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor and shall share equally on a per share basis in such dividends and distributions, provided that such holder is not an Unsuitable Person (as defined below).

Liquidation, Dissolution and Winding-Up

In the event of our voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of our common stock will be entitled to receive an equal amount per share of all of our assets of whatever kind available for distribution to stockholders, after the rights of our creditors and the rights of holders of Preferred Stock, if any, have been satisfied.

Preemptive or Other Rights

There are no sinking fund provisions applicable to the common stock. Our stockholders have no preemptive or other subscription rights.

Preferred Stock

Our board of directors has the authority to issue up to an aggregate of 10,000,000 shares of Preferred Stock in one or more series, and to fix the designations, preferences, rights, qualifications, limitations and restrictions thereof or thereon, without any further vote or action by the stockholders. No shares of Preferred Stock are outstanding as of the date hereof.

You should refer to any filing with the SEC relating to the series of preferred stock being offered for the specific terms of that series, including:

- the title of the series and the number of shares in the series;
- the price at which the preferred stock will be offered;
- the dividend rate or rates or method of calculating the rates, the dates on which the dividends will be payable, whether or not dividends will be cumulative or noncumulative and, if cumulative, the dates from which dividends on the preferred stock being offered will cumulate;
- the voting rights, if any, of the holders of shares of the preferred stock being offered;
- the provisions for a sinking fund, if any, and the provisions for redemption, if applicable, of the preferred stock being offered, including any restrictions on the foregoing as a result of arrearage in the payment of dividends or sinking fund installments;
- the liquidation preference per share;
- the terms and conditions, if applicable, upon which the preferred stock being offered will be convertible into our common stock, including the conversion price, or the manner of calculating the conversion price, and the conversion period;
- the terms and conditions, if applicable, upon which the preferred stock being offered will be exchangeable for debt securities, including the exchange price, or the manner of calculating the exchange price, and the exchange period;
- any listing of the preferred stock being offered on any securities exchange;
- a discussion of any material federal income tax considerations applicable to the preferred stock being offered;
- any preemptive rights;
- the relative ranking and preferences of the preferred stock being offered as to dividend rights and rights upon liquidation, dissolution or the winding up of our affairs;
- any limitations on the issuance of any class or series of preferred stock ranking senior or equal to the series of preferred stock being offered as to dividend rights and rights upon liquidation, dissolution or the winding up of our affairs; and
- any additional rights, preferences, qualifications, limitations and restrictions of the series.

Upon issuance, the shares of preferred stock will be fully paid and nonassessable, which means that its holders will have paid their purchase price in full and we may not require them to pay additional funds.

Any preferred stock terms selected by our board of directors could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and power, including voting rights, of the holders of our common stock without any further vote or action by the stockholders. The rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued by us in the future. The issuance of preferred stock could also have the effect of delaying or preventing a change in control of our company or make removal of management more difficult.

Our Charter and Bylaws contain provisions that could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors. These provisions include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director with or without cause by stockholders, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to determine whether to issue shares of our Preferred Stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- limiting the liability of, and providing indemnification to, our directors and officers;
- specifying the Court of Chancery of the State of Delaware as the exclusive forum for adjudication of disputes;
- controls over the procedures for the conduct and scheduling of stockholder meetings; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions, singly or together, could delay hostile takeovers and changes in control of us or changes in our board of directors and management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock. Any provision of our Charter or Bylaws, or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

As of March 27, 2023, there is a warrant outstanding exercisable for 800,000 shares of common stock (the “Warrant”).

The Warrant was originally issued in connection with a loan and security agreement between us and MidCap. Pursuant to the terms of the Warrant Agreement, the Warrant entitles the registered holder can purchase 800,000 shares of the Company’s common stock at an exercise price equal to \$0.88 for a period ending on June 30, 2033. The Company has registered the shares underlying the Warrant, .

The Warrant provides that the holder thereof may elect to exercise the warrant on a net “cashless” basis at any time prior to the expiration thereof. Pursuant to a registration rights agreement, we agreed to file a registration statement covering the resale of the shares underlying the Warrant June 30, 2023.

In connection with a Merger Event (defined below) that is a Liquid Sale (defined below) where the value per share of our common stock is greater than the exercise price then in effect, the Warrant shall, on and after the closing of the Merger Event, automatically and without further action on the part of any party or other person, represent the right to receive, in lieu of the shares of our common stock that are issuable under the Warrant Agreement as of immediately prior to the closing of such Merger Event, the consideration payable on or in respect of such shares of our common stock less the amount equal to then-effective exercise price multiplied by the number of shares of our common stock as to which the Warrant is then exercised (such amount being the “purchase price”) for all such shares of our common stock (such consideration to include both the consideration payable at the closing of such Merger Event and all deferred consideration payable thereafter, if any, including, but not limited to, payments of amounts deposited at such closing into escrow and payments in the nature of earn-outs, milestone payments or other performance-based payments), and such Merger Event consideration shall be paid to the holder of the Warrant as and when it is paid to the holders of the outstanding shares of our common stock; provided, however, in the event of a Merger Event that is an arm’s length sale of all or substantially all of our assets (and only its assets) to a third party that is not an affiliate of us (a “True Asset Sale”), the holder of the Warrant may either (a) exercise its conversion or purchase right under the Warrant and such exercise will be deemed effective immediately prior to the consummation of such Merger Event, or (b) permit the Warrant to continue for the term of the Warrant Agreement if we continue as a going concern following the closing of any such True Asset Sale. In connection with a Merger Event that is not a Liquid Sale, we shall cause the successor or surviving entity to assume the Warrant Agreement and our obligations thereunder on the closing thereof, and thereafter the Warrant shall be exercisable for the same number, class, and type of securities or other property as the holder of the Warrant would have received in consideration for the shares of our common stock issuable under the Warrant Agreement had it exercised the Warrant in full as of immediately prior to such closing, at an aggregate exercise price no greater than the aggregate exercise price in effect as of immediately prior to such closing, and subject to further adjustment from time to time in accordance with the provisions of this Agreement. This provision shall similarly apply to successive Merger Events. For purposes of this section of the Prospectus:

- A “Merger Event” means any of the following: (i) a sale, lease or other transfer of all or substantially all of our assets, (ii) any merger or consolidation involving us in which we are not the surviving entity or in which our outstanding shares of capital stock are otherwise converted into or exchanged for shares of capital stock or other securities or property of another entity or converted into the right to receive cash, or (iii) any sale by holders of our outstanding voting equity securities in a single transaction or series of related transactions of shares constituting a majority of the outstanding combined voting power of us; and
-

- A “Liquid Sale” means the closing of a Merger Event in which the consideration received by us and/or our stockholders, as applicable, consists solely of cash and/or securities meeting all of the following requirements:
 - o the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act and is then current in its filing of all required reports and other information under the Act and the Exchange Act;
 - o the class and series of shares or other security of the issuer that would be received by the holder of the Warrant in connection with the Merger Event were the holder to exercise the Warrant on or prior to the closing thereof is then traded on a national securities exchange or over-the-counter market; and
 - o following the closing of such Merger Event, the holder of the Warrant would not be restricted from publicly re-selling all of the issuer’s shares and/or other securities that would be received by the holder in such Merger Event were the holder to exercise the Warrant in full on or prior to the closing of such Merger Event, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Merger Event.

Except for Merger Events discussed above, if we at any time shall, by combination, reclassification, exchange or subdivision of securities or otherwise, change any of the securities as to which purchase rights under the Warrant Agreement exist into the same or a different number of securities of any other class or classes of securities, the Warrant Agreement shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities which were subject to the purchase rights under the Warrant Agreement immediately prior to such combination, reclassification, exchange, subdivision or other change. This provision shall similarly apply to successive combination, reclassification, exchange, subdivision or other change.

If we at any time shall combine or subdivide our common stock, (i) in the case of a subdivision, the exercise price of the Warrant shall be proportionately decreased and the number of shares for which the Warrant is exercisable shall be proportionately increased, or (ii) in the case of a combination, the exercise price of the Warrant shall be proportionately increased and the number of shares for which the Warrant is exercisable shall be proportionately decreased.

If we at any time while the Warrant Agreement is outstanding and unexpired shall pay a dividend with respect to the outstanding shares of our common stock payable in additional shares of our common stock, then the exercise price of the Warrant shall be adjusted to that price determined by multiplying the exercise price in effect immediately prior to such date of determination by a fraction (i) the numerator of which shall be the total number of shares of our common stock outstanding immediately prior to such dividend or distribution, and (ii) the denominator of which shall be the total number of shares of our common stock outstanding immediately after such dividend or distribution, and the number of shares of our common stock for which the Warrant is exercisable shall be proportionately increased.

If we at any time while the Warrant Agreement is outstanding and unexpired shall make any other dividend or distribution on or with respect to our common stock, except any dividend or distribution (i) in cash, or (ii) specifically provided for in any other clause of the Warrant Agreement, then, in each such case, provision shall be made by us such that the holder of the Warrant shall receive upon exercise or conversion of the Warrant a proportionate share of any such distribution as though it were the holder of our common stock (or other stock for which our common stock is convertible) as of the record date fixed for the determination of our stockholders entitled to receive such distribution.

AMENDMENT NO. 5 TO CREDIT AND SECURITY AGREEMENT

This AMENDMENT NO. 5 TO CREDIT AND SECURITY AGREEMENT (this “**Agreement**”) is made as of this **27th** day of March, 2024 (“**Effective Date**”), by and among **STRATA SKIN SCIENCES, INC.**, a Delaware corporation (together with each of its subsidiaries that hereafter becomes a party to this Agreement, the “**Borrower**”), **MIDCAP FINANCIAL TRUST**, as Agent for Lenders (in such capacity and together with its permitted successors and assigns, the “**Agent**”) and the other financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders and Borrower have entered into that certain Credit and Security Agreement, dated as of September 30, 2021 (as amended by that certain Limited Consent and Amendment No. 1 to Credit and Security Agreement, dated as of January 10, 2022, that certain Amendment No. 2 to Credit and Security Agreement, dated as of September 6, 2022, that certain Amendment No. 3 to Credit and Security Agreement, dated as of June 30, 2023 and that certain Limited Waiver and Amendment No. 4 to Credit and Security Agreement, dated as of February 20, 2024 and as further amended, restated, supplemented or otherwise modified from time to time prior to the date hereof, the “**Existing Credit Agreement**” and the Existing Credit Agreement, as amended hereby, the “**Credit Agreement**”), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrower in the amounts and manner set forth in the Credit Agreement.

B. Borrower has requested, and Agent and Lenders have agreed, to enter into this Agreement, all in accordance with the terms and subject to the conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent, Lenders, and the Borrower hereby agree as follows:

1. **Recitals; Construction.** This Agreement shall constitute a Financing Document and the Recitals and each reference to the Credit Agreement, unless otherwise expressly noted, will be deemed to reference the Credit Agreement as modified hereby. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Credit Agreement (including those capitalized terms used in the Recitals hereto).

2. **Amendments to Existing Credit Agreement.** Subject to the terms and conditions of this Agreement, including, without limitation, the conditions to effectiveness set forth in Section 4 below, the Existing Credit Agreement is hereby amended as follows:

(a) Section 6.6(b) of the Existing Credit Agreement is hereby amended and restated as follows:

“The provisions of the previous sentence shall not apply to Excluded Accounts. At all times following the post-closing period set forth on the Post-Closing Obligations Schedule, Borrower shall maintain one or more Payroll Accounts.”

(b) The following definitions of “ACH Accounts”, “Excluded Accounts” and “Payroll Accounts” are hereby added to Section 15 of the Existing Credit Agreement in the appropriate alphabetical order therein:

“**ACH Accounts**” means any segregated cash collateral Deposit Account established by a Credit Party for the sole purpose of securing such Credit Party’s obligations in respect of drawn or committed but unpaid draft ACH transactions and identified to Agent by Credit Parties as such and in which there is not maintained at any point funds on deposit of greater than One Hundred Twenty Five Thousand Dollars (\$125,000) in the aggregate for all such accounts.

“**Excluded Accounts**” means (a) any Payroll Account, and (b) any ACH Account.

“**Payroll Accounts**” means any deposit accounts exclusively used for payroll, payroll taxes and, in Agent’s discretion, other employee wage and benefit payments to or for the benefit of a Credit Party’s employees and identified to Agent by Borrower as such and provided, that the aggregate balance in such Payroll Accounts does not exceed the amount necessary to make the immediately succeeding payroll, payroll tax or benefit payment (or such minimum amount as may be required by any requirement of Law with respect to such accounts).

(c) The definition of “Permitted Liens” in Section 15 of the Existing Credit Agreement is hereby amended by:

(i) deleting the “and” at the end of clause (j) thereof:

(ii) adding the following as new clause (k) in the appropriate alphabetical order therein; and

“(k) Liens solely in respect of the ACH Accounts and amounts deposited therein to the extent securing obligations in respect of drawn or committed but unpaid draft ACH transactions incurred in the Ordinary Course of Business.

(iii) renumbering the existing clause (k) as new clause (l) therein.

3. **Representations and Warranties; Reaffirmation of Security Interest.** Each Credit Party hereby confirms that all of the representations and warranties set forth in the Credit Agreement are true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) with respect to such Credit Party as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects as of such earlier date. Each Credit Party reaffirms its obligations under each Security Document to which it is a party, and confirms and agrees that all security interests and Liens granted to the Agent continue in full force and effect. Nothing herein is intended to impair or limit the validity, priority or extent of Agent’s security interests in and Liens on the Collateral. Each Credit Party acknowledges and agrees that the Credit Agreement, the other Financing Documents and this Agreement constitute the legal, valid and binding obligation of such Credit Party, and are enforceable against such Credit Party in accordance with its terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws relating to the enforcement of creditors’ rights generally and by general equitable principles.

4. **Conditions to Effectiveness.** This Agreement shall become effective as of the date on which each of the following conditions has been satisfied, as determined by Agent in its sole discretion:

(a) Agent shall have received a duly authorized, executed and delivered counterpart of the signature page to this Agreement from Borrower, Agent and the Lenders;

(b) all representations and warranties of Borrowers contained herein shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects (or, in the case of any representation or warranty that is, by its terms, qualified by materiality, in all respects) as of such earlier date (and such parties' delivery of their respective signatures hereto shall be deemed to be its certification thereof);

(c) prior to and after giving effect to the agreements set forth herein, no Default or Event of Default shall exist under any of the Financing Documents; and

(d) the Borrowers shall have delivered such other documents, information, certificates, records, permits and filings as Agent may reasonably request.

5. **Costs and Fees.** Borrowers shall be responsible for the payment of all reasonable, documented and invoiced out-of-pocket costs and fees of Agent's counsel incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and any related Financing Documents.

6. **Release.** In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each Credit Party, voluntarily, knowingly, unconditionally and irrevocably, with specific and express intent, for and on behalf of itself and all of its respective parents, subsidiaries, affiliates, members, managers, predecessors, successors, and assigns, and each of their respective current and former directors, officers, shareholders, agents, and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Releasing Parties**") does hereby fully and completely release, acquit and forever discharge each of Agent, Lenders, and each their respective parents, subsidiaries, affiliates, members, managers, shareholders, directors, officers and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Released Parties**"), of and from any and all actions, causes of action, suits, debts, disputes, damages, claims, obligations, liabilities, costs, expenses and demands of any kind whatsoever, at law or in equity, whether matured or unmatured, liquidated or unliquidated, vested or contingent, choate or inchoate, known or that reasonably should have been known that the Releasing Parties (or any of them) has against the Released Parties or any of them (whether directly or indirectly), based in whole or in part on facts, known or that reasonably should have been known, existing on or before the date hereof. Each Credit Party acknowledges that the foregoing release is a material inducement to Agent's and each Lender's decision to enter into this Agreement and agree to the modifications contemplated hereunder, and has been relied upon by Agent and Lenders in connection therewith.

7. **No Waiver or Novation.** The execution, delivery and effectiveness of this Agreement shall not operate as a waiver of any right, power or remedy of Agent, nor constitute a waiver of any provision of the Credit Agreement, the Financing Documents or any other documents, instruments and agreements executed or delivered in connection with any of the foregoing. Nothing herein is intended or shall be construed as a waiver of any existing Defaults or Events of Default under the Credit Agreement or other Financing Documents or any of Agent's rights and remedies in respect of such Defaults or Events of Default. This Agreement (together with any other document executed in connection herewith) is not intended to be, nor shall it be construed as, a novation of the Credit Agreement.

8. **Affirmation.** Except as specifically amended pursuant to the terms hereof, each Credit Party hereby acknowledges and agrees that the Existing Credit Agreement and all other Financing Documents (and all covenants, terms, conditions and agreements therein) shall remain in full force and effect, and are hereby ratified and confirmed in all respects by such Credit Party, including without limitation the granting of Liens in the Collateral to secure the Obligations and other Financing Documents. Each Credit Party covenants and agrees to comply with all of the terms, covenants and conditions of the Credit Agreement and the other Financing Documents, notwithstanding any prior course of conduct or other actions or inactions on Agent's or any Lender's part which might otherwise constitute or be construed as a waiver of or amendment to such terms, covenants and conditions. Each Credit Party confirms and agrees that all security interests and Liens granted to Agent pursuant to the Financing Documents continue in full force and effect, and all Collateral remains free and clear of any Liens, other than those granted to Agent and Permitted Liens.

9. **Miscellaneous.**

(a) **Reference to the Effect on the Credit Agreement.** The Credit Agreement, and all other Financing Documents (and all covenants, terms, conditions and agreements therein), shall remain in full force and effect, and are hereby ratified and confirmed in all respects by each Credit Party.

(b) THIS AGREEMENT AND THE RIGHTS, REMEDIES AND OBLIGATIONS OF THE PARTIES HERETO, AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT, THE RELATIONSHIP OF THE PARTIES, AND/OR THE INTERPRETATION AND ENFORCEMENT OF THE RIGHTS AND DUTIES OF THE PARTIES AND ALL OTHER MATTERS RELATING HERETO OR ARISING THEREFROM (WHETHER SOUNDING IN CONTRACT LAW, TORT LAW OR OTHERWISE), SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REFERENCE TO ITS CONFLICT OF LAW PROVISIONS (OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW). NOTWITHSTANDING THE FOREGOING, AGENT AND LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST EACH CREDIT PARTY OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH AGENT AND LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 12.1 OF THE CREDIT AGREEMENT) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE AGENT'S AND LENDERS' RIGHTS AGAINST SUCH CREDIT PARTY OR ITS PROPERTY. EACH CREDIT PARTY EXPRESSLY SUBMITS AND CONSENTS IN ADVANCE TO SUCH JURISDICTION IN ANY ACTION OR SUIT COMMENCED IN ANY SUCH COURT, AND EACH CREDIT PARTY HEREBY WAIVES ANY OBJECTION THAT IT MAY HAVE BASED UPON LACK OF PERSONAL JURISDICTION, IMPROPER VENUE, OR FORUM NON CONVENIENS AND HEREBY CONSENTS TO THE GRANTING OF SUCH LEGAL OR EQUITABLE RELIEF AS IS DEEMED APPROPRIATE BY SUCH COURT. EACH CREDIT PARTY HEREBY WAIVES PERSONAL SERVICE OF THE SUMMONS, COMPLAINTS, AND OTHER PROCESS ISSUED IN SUCH ACTION OR SUIT AND AGREES THAT SERVICE OF SUCH SUMMONS, COMPLAINTS, AND OTHER PROCESS MAY BE MADE BY REGISTERED OR CERTIFIED MAIL ADDRESSED TO THE APPLICABLE CREDIT PARTY AT THE ADDRESS SET FORTH IN ARTICLE 11 OF THE CREDIT AGREEMENT AND THAT SERVICE SO MADE SHALL BE DEEMED COMPLETED UPON THE EARLIER TO OCCUR OF SUCH CREDIT PARTY'S ACTUAL RECEIPT THEREOF OR THREE (3) DAYS AFTER DEPOSIT IN THE U.S. MAIL, PROPER POSTAGE PREPAID.

(c) **TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, EACH CREDIT PARTY, AGENT AND LENDERS PARTY HERETO EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR BOTH PARTIES TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

(d) Incorporation of Credit Agreement Provisions. The provisions contained in Section 12.2(b) (*California Waivers*), Section 12.3 (*California Waiver*) and Section 13.2 (*Indemnification*) of the Credit Agreement are incorporated herein by reference to the same extent as if reproduced herein in their entirety.

(e) Headings. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

(f) Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed signature page of this Agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof. In furtherance of the foregoing, the words “execution”, “signed”, “signature”, “delivery” and words of like import in or relating to any document to be signed in connection with this Agreement and the transactions contemplated hereby or thereby shall be deemed to include Electronic Signatures, deliveries or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature, physical delivery thereof or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act. As used herein, “Electronic Signature” means an electronic sound, symbol, or process attached to, or associated with, a contract or other record and adopted by a Person with the intent to sign, authenticate or accept such contract or other record.

(g) Entire Agreement. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes any and all prior agreements and understandings, oral or written, relating to the subject matter hereof.

(h) Severability. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any applicable jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(i) Successors/Assigns. This Agreement shall bind, and the rights hereunder shall inure to, the respective successors and assigns of the parties hereto, subject to the provisions of the Credit Agreement and the other Financing Documents.

[SIGNATURES APPEAR ON FOLLOWING PAGES]

IN WITNESS WHEREOF, intending to be legally bound, the undersigned have executed this Agreement as of the day and year first hereinabove set forth.

AGENT:

MIDCAP FINANCIAL TRUST

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: _____

Name: Maurice Amsellem

Title: Authorized Signatory

Signature Page(s)

LENDERS:

MIDCAP FINANCIAL TRUST

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: _____
Name: Maurice Amsellem
Title: Authorized Signatory

Signature Page(s)

LENDERS:

MIDCAP FUNDING XLIX TRUST

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: _____
Name: Maurice Amsellem
Title: Authorized Signatory

Signature Page(s)

LENDERS:

ELM 2020-3 TRUST

By: MidCap Financial Services Capital Management,
LLC, as Servicer

By: _____
Name: John O'Dea
Title: Authorized Signatory

ELM 2020-4 TRUST

By: MidCap Financial Services Capital Management,
LLC, as Servicer

By: _____
Name: John O'Dea
Title: Authorized Signatory

Signature Page(s)

BORROWER:

STRATA SKIN SCIENCES, INC.

By: _____

Name: C. Lesovitz

Title: CFO

MidCap / Strata / Amendment No. 5

STRATA SKIN SCIENCES, INC.

CLAWBACK POLICY

Introduction

The Board of Directors of the Company (the “**Board**”) believes that it is in the best interests of STRATA Skin Sciences, Inc. (the “**Company**”) and its stockholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company’s pay-for-performance compensation philosophy. The Board has therefore adopted this policy which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the “**Policy**”). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934 (the “**Exchange Act**”) and Nasdaq Listing Rule 5608 (the “**Clawback Listing Standards**”).

Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals. Subject to any limitation at applicable law, the Board or, if applicable, the Compensation Committee, may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

Covered Executives

This Policy applies to the Company’s current and former executive officers, as determined by the Board in accordance with the definition in Section 10D of the Exchange Act and the Clawback Listing Standards (“**Covered Executives**”), and applies to Incentive-Based Compensation (defined below) received by a Covered Executive (a) after beginning services as a Covered Executive; (b) if that person served as a Covered Executive at any time during the performance period for such Incentive-Based Compensation; and (c) while the Company had a listed class of securities on a national securities exchange.

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Board will require reimbursement or forfeiture of any excess Incentive Compensation received by any Covered Executive except for any Covered Executive excluded per the "Covered Executives" paragraph above (namely: a Covered Executive who received Incentive Based Compensation (a) after beginning services as a Covered Executive; (b) if that person served as a Covered Executive at any time during the performance period for such Incentive-Based Compensation; and (c) while the Company had a listed class of securities on a national securities exchange), during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement. The **"date on which the Company is required to prepare an accounting restatement"** is the earlier to occur of (a) the date the Board or a committee thereof, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement or (b) the date a court, regulator or other legally authorized body directs the Company to prepare an accounting restatement, in each case regardless of if or when the restated financial statements are filed.

Incentive Compensation

For purposes of this Policy, Incentive Compensation means any of the following; provided that, such compensation is granted, earned, or vested based wholly or in part on the attainment of a financial reporting measure:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.

Financial reporting measures include:

- Revenues.
- Net income.
- Earnings before interest, taxes, depreciation, and amortization (EBITDA).

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Board, without regard to any taxes paid by the Covered Executive in respect of the Incentive Compensation paid based on the erroneous data.

If the Board cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement.

Method of Recoupment

The Board will determine, in its sole discretion, the method for recouping Incentive Compensation hereunder which may include, without limitation:

- (a) requiring reimbursement of cash Incentive Compensation previously paid;
- (b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- (c) offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
- (d) cancelling outstanding vested or unvested equity awards; and/or
- (e) taking any other remedial and recovery action permitted by law, as determined by the Board.

No Indemnification

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Incentive Compensation.

Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, any applicable rules or standards adopted by the Securities and Exchange Commission, and the Clawback Listing Standards.

Effective Date

This Policy shall be effective as of October 2, 2023 (the “**Effective Date**”) and shall apply to Incentive Compensation that is received by Covered Executives on or after the Effective Date, even if such Incentive Compensation was approved, awarded, or granted to Covered Executives prior to the Effective Date.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect final regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act and to comply with the Clawback Listing Standards and any other rules or standards adopted by a national securities exchange on which the Company’s securities are listed. The Board may terminate this Policy at any time.

Other Recoupment Rights

Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Relationship to Other Plans and Agreements

The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. In the event of any inconsistency between the terms of the Policy and the terms of any employment agreement, equity award agreement, or similar agreement under which Incentive Compensation has been granted, awarded, earned or paid to a Covered Executive, whether or not deferred, the terms of the Policy shall govern.

Acknowledgment

The Covered Executive shall sign an acknowledgment form in the form attached hereto as Exhibit A in which they acknowledge that they have read and understand the terms of the Policy and are bound by the Policy.

Impracticability

The Board shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with Rule 10D-1 of the Exchange Act and the listing standards of the national securities exchange on which the Company’s securities are listed.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

EXHIBIT A

STRATA SKIN SCIENCES, INC.

CLAWBACK POLICY

ACKNOWLEDGEMENT FORM

I, the undersigned, agree and acknowledge that I am fully bound by, and subject to, all of the terms and conditions of the Strata Skin Sciences, Inc. Clawback Policy (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Policy**"). In the event of any inconsistency between the Policy and the terms of any employment agreement to which I am a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern. In the event it is determined by the Committee that any amounts granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I acknowledge and agree that I am and will continue to be subject to the Policy and that the Policy will apply both during and after my employment with the Company. Any capitalized terms used in this Acknowledgment without definition shall have the meaning set forth in the Policy.

COVERED EXECUTIVE

Signature

Print Name

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of STRATA Skin Sciences, Inc. and Subsidiary on Form S-3 (File No.'s 333-273846, 333-262150, 333-261090 and 333-258814) and Form S-8 (File No. 333-257867) of our report dated March 27, 2024, with respect to our audits of the consolidated financial statements of STRATA Skin Sciences, Inc. and Subsidiary as of December 31, 2023 and 2022 and for the years ended December 31, 2023 and 2022, which report is included in this Annual Report on Form 10-K of STRATA Skin Sciences, Inc. and Subsidiary for the year ended December 31, 2023.

/s/ Marcum LLP

Marcum LLP
Philadelphia, Pennsylvania
March 27, 2024

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Dolev Rafaeli, certify that:

- (1) I have reviewed this annual report on Form 10-K of STRATA Skin Sciences, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 27, 2024

STRATA SKIN SCIENCES, INC.

By: /s/ Dolev Rafaeli

Dolev Rafaeli

President & Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Christopher Lesovitz, certify that:

- (1) I have reviewed this annual report on Form 10-K of STRATA Skin Sciences, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 27, 2024

STRATA SKIN SCIENCES, INC.

By: /s/ Christopher Lesovitz

Christopher Lesovitz
Chief Financial Officer

SECTION 906 CERTIFICATION

CERTIFICATION (1)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Dolev Rafaeli, the President and Chief Executive Officer of STRATA Skin Sciences, Inc. (the "Company"), and Christopher Lesovitz, the Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 27, 2024

/s/ Dolev Rafaeli

Dolev Rafaeli
President & Chief Executive Officer

/s/ Christopher Lesovitz

Christopher Lesovitz
Chief Financial Officer

- (1) This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of STRATA Skin Sciences, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to STRATA Skin Sciences, Inc. and will be retained by STRATA Skin Sciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.