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, 2022

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	13-3986004
(State or Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
5 Walnut Grove Drive, Suite 140 Horsham, Pennsylvania	19044
(Address of principal executive offices)	(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, 2022 was 34,723,046 shares. The aggregate market value of voting and non-voting common equity held by non-affiliates on the registrant was $17,222,777, computed by reference to the closing market price of $0.96 of the common stock as of June 30, 2022 and 17,940,393 shares held by non-affiliates. As of March 15, 2023, the number of shares outstanding of our common stock was 34,881,453.

Documents incorporated by reference:

Portions of the proxy statement relating to STRATA Skin Sciences, Inc.'s 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This 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 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 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. On January 5, 2016, we changed our name to STRATA Skin 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. 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.

Impact of COVID-19 Pandemic

In late 2019, there was an outbreak of a new strain of coronavirus ("COVID-19") which became a global pandemic. While many of COVID-19's initial disruptions and damage to the global economy have been mitigated, the COVID-19 pandemic has continued to negatively impact the economy, 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 ongoing 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, the ongoing mutations and spread of the COVID-19 virus, impact on business operations, supply chains, and transport, and governmental and societal responses thereto, all of which are uncertain and cannot be predicted.

The ongoing COVID-19 pandemic has had a negative impact on our results of operations and financial performance through fiscal 2022, and we expect it will continue to have a negative impact on revenues, earnings and cash flows until such time as our customers adjust to the pandemic's ramifications. Some physician offices continue to experience staffing issues, and we believe these shortages of trained personnel have negatively impacted our business. Accordingly, current results and financial conditions discussed herein may not be indicative of future operating results and trends.

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. 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 supporters 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 war have raised the price of gas significantly 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 disruptions caused by this war.

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 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 909 systems were, as of December 31, 2022, included in our dermatology recurring procedures revenue model. The Pharos business provides the opportunity for us to convert the 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.

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. There are three applicable 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 $162 per treatment to $240 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 currently approximately 76% of insurers consider XTRAC treatments to be medically necessary for the treatment of vitiligo and therefore provide coverage.

We believe that several factors have limited the growth of the use of XTRAC treatments from 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, but we continue to sell this product on a purchase order basis.

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 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, 2022, 28 issued U.S. patents are in force, and many of these patents have foreign counterparts issued and pending. The Company maintains 15 patents from Mela Sciences, Inc. related to the 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, STRATAPEN 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 and we purchase our STRATAPEN devices from third parties, who are subject to the same regulations. We rely on these third parties 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, 2022, the national rates were as follows:

- 96920 – designated for: the total area less than 250 square centimeters. CMS assigned a 2022 national payment of $162 per treatment;
- 96921 – designated for: the total area 250 to 500 square centimeters. CMS assigned a 2022 national payment of $176 per treatment; and
- 96922 – designated for: the total area over 500 square centimeters. CMS assigned a 2022 national payment of $240 per treatment.

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

Employees

As of December 31, 2022, we had 114 full-time employees, which consisted of 2 executive officers, 3 vice presidents, 60 sales and marketing staff, 17 people engaged in manufacturing of lasers, 16 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, 2022, we have 909 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.

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 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 Report and is intended to be an inactive textual reference only.

ITEM 1A. RISK FACTORS

In addition to the other information contained in this 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.
- Our results of operations have been, and may continue to be, negatively impacted by COVID-19 or other future outbreak of any other highly infectious or contagious diseases.
- 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 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.
- 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.
- The continuing development of our products depends upon our developing and maintaining strong working relationships with physicians.
- 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.
- 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.
- 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 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.
- 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.
- Our medical device operations are subject to FDA regulatory requirements.
- 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.
- Consolidation in the medical device industry could have an adverse effect on our revenue 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.
- 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 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.

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

- 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.

- 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, 2022 was approximately $5.5 million, and as of December 31, 2022, we had an accumulated deficit of approximately $227 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. We believe that our cash and cash equivalents as of December 31, 2022, combined with the anticipated revenues from the sale of our product and operating expense management, will be sufficient to satisfy our working capital needs, lasers placed-in-service, capital asset purchases, outstanding commitments and other liquidity requirements associated with our existing operations through at least the next 12 months following the filing of this Report.

Our results of operations have been, and may continue to be, negatively impacted by COVID-19 or other future outbreak of any other highly infectious or contagious diseases.

In December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China. COVID-19 has since spread to over 100 countries, including every state in the United States. In the last 36 months, the United States and the world have experienced various levels of government shutdowns, closures and quarantines.

The outbreak of COVID-19 has severely impacted global economic activity and caused significant volatility and negative pressure in financial markets, global supply chains, labor supply and inflation. This outbreak has triggered a period of global economic slowdown and a change in the behavior of the ultimate consumer of our products and services, which could continue for some time which cannot be predicted. COVID-19 or another pandemic has or could have material and adverse effects on our ability to successfully operate our business due to, among other factors:

- a general decline in business activity;
- the destabilization of the markets and negative impacts on the healthcare system globally 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;
- 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;
- the potential negative impact on the health of our employees, especially if a significant number of them are impacted;
- the impact of the pandemic on our customers, which may result in a decrease in the use of our products and services as well as an increase in past due accounts receivable, write-offs and customer bankruptcies; and
- a deterioration in our ability to ensure business continuity during a disruption.

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 raised the price of gas significantly 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. 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.

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.

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.

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, 2021, we estimate, based on published coverage policies and on payment practices of private and Medicare insurance plans, 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.

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 under our debt and could divert our cash flow from operations for debt payments.

In September 2021, we entered into an $8.0 million secured borrowing facility (the "Senior Credit Facility") with MidCap. The Senior Credit Facility bears interest at LIBOR plus 7.50%, with a LIBOR floor of 0.50%, and matures on September 1, 2026. In September 2022, we amended the Senior Credit 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%. We are obligated to make interest-only payments through September 2024. From October 2024 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 revenue thresholds. Upon an event of default, including a covenant violation, all principal and interest are due on demand. 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 2022, 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 $20 thousand during 2023.

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. As discussed above, we amended the Senior Credit Facility to transition to SOFR upon such occurrence. 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 two assessments, an aggregate amount of $1.5 million for the period from March 2014 through February 2020 including penalties and interest. 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. 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 and, on May 6, 2022, we received a written decision from the State of New York Tax Appeals Tribunal (the "Tribunal") overturning the favorable sales tax determination of the administrative law judge. We filed an appeal of the Tribunal's decision, and posted the required appellate bond, with the New York State Appellate Division. We are waiting for the appellate court to set a briefing and oral argument schedule. The second jurisdiction has made an assessment of $0.7 million from June 2015 through March 2018 plus interest of $0.2 million through April 2020. We are in the administrative appeal process in this jurisdiction as well and the timing has been impacted by the COVID-19 pandemic. 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, 2022 and 2021, we have estimated our sales and use tax liability to be approximately $4.0 million and $3.7 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. 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 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, although based upon our cash and cash equivalents, current budgeting and projected cash flow models, we believe that we will be able to support our operations for at least the next 12 months following the filing of this Report. 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 back-ups with offsite retention of storage media, system audits, data partitioning, routine password modifications and disaster recovery procedures, such measures may not be adequate or implemented properly to prevent or fully address the adverse effect of such events. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

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

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.

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 listed on the Nasdaq Capital Market ("Nasdaq CM"), which imposes, among other requirements, a minimum $1.00 per share bid price requirement for continued inclusion on the Nasdaq CM pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). The closing bid price for our common stock must remain at or above $1.00 per share to comply with the Bid Price Requirement for continued listing. On October 26, 2022, we received a deficiency letter (the "Notice") from the Listing Qualifications Department of the Nasdaq Stock Market, LLC ("Nasdaq") notifying us that, for the preceding 30 consecutive trading days, the closing bid price of our common stock was below the Bid Price Requirement. On February 27, 2023, we announced that we had regained compliance with the Bid Price Requirement. Given market volatility and business conditions, we cannot assure you that we will continue to maintain compliance under the current economic climate.

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 September 2021, we issued a warrant to MidCap Financial Trust to purchase 373,626 shares of our common stock, with an exercise price of $1.82 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 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. The lease was set to expire on September 30, 2019. 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 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 through mediation. The mediation was held on February 23, 2023, and the matter was settled on terms agreeable to the Company. The settlement, which would require us to pay $0.1 million, is tentative and subject to court approval and the right of individual class members to reject the settlement and proceed on their own.

We are currently under audit by two taxing jurisdictions, pertaining to sales and/or use tax. One jurisdiction has assessed us an amount of $1.5 million including penalties and interest, in two assessments, for the period from March 2014 through February 2020. We have declined an informal offer to settle the first assessment at a substantially lower amount and are currently in that jurisdiction's administrative process of appeal.

In January 2021, we received notification that the administrative law judge had issued an opinion finding in favor of us that the sale of XTRAC treatment codes is not taxable as sales tax with respect to the 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, we received a written decision from the Taxing Authority's Appeals Tribunal ("Tribunal") overturning the favorable sales tax determination of the administrative law judge. We filed an appeal of the Tribunal's decision, and posted the required appellate bond requiring posting cash collateral, with the appellate court, and are awaiting for the appellate court to set a briefing and oral argument schedule.

A second jurisdiction has made an assessment of $0.7 million from June 2015 through March 2018 plus interest of $0.2 million through April 2020. We are in this jurisdiction's administrative process of appeal as well and the timing of the process has been impacted by the COVID-19 pandemic. If it is found we are not exempt from sales tax in these or other states then potential tax liabilities including interest and penalties would be higher than accrued amounts**.**

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 15, 2023, we had 34,881,453 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 4,464,714 shares of common stock, of which 2,368,841 were vested as of March 15, 2023, (ii) unissued restricted stock units of 119,597, or (iii) 373,626 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, 2022. See Notes 1 and 14 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	4,474,714	$ 1.72	3,193,706
Equity compensation plans not approved by security holders	—	—	—
	4,474,714	$ 1.72	3,193,706

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 now 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, 2022, there were 909 XTRAC systems placed in dermatologists' offices in the United States under our dermatology recurring procedures model, an increase from 890 at the end of December 31, 2021. 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. 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.

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.

The Pharos excimer laser system holds FDA clearance to treat chronic skin diseases, including psoriasis, vitiligo, atopic dermatitis and leukoderma.

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.

COVID-19 Pandemic

In late 2019, there was an outbreak of a new strain of coronavirus ("COVID-19") which became a global pandemic. While many of COVID-19's initial disruptions and damage to the global economy have been mitigated, the COVID-19 pandemic has continued to negatively impact the economy, 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 ongoing 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, the ongoing mutations and spread of the COVID-19 virus, impact on business operations, supply chains and transport, and governmental and societal responses thereto, all of which are uncertain and cannot be predicted.

The ongoing COVID-19 pandemic has had a negative impact on our results of operations and financial performance through fiscal 2022, and we expect it will continue to have a negative impact on revenues, earnings and cash flows until such time as its customers adjust to the pandemic's ramifications. Some physician offices continue to experience staffing issues, and we believe these shortages of trained personnel have negatively impacted our business. Accordingly, current results and financial conditions discussed herein may not be indicative of future operating results and trends.

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. 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 supporters 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 war have raised the price of gas significantly 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 disruptions caused by this war.

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

Asset Acquisitions

Pharos Laser Acquisition. In August 2021 we acquired certain assets and certain liabilities related to the Pharos U.S. dermatology business of Ra Medical Systems, Inc. ("Ra Medical"). The Pharos asset acquisition provides us with the opportunity to market our full business solutions to Ra Medical's existing customer base of 400 dermatology practices and increase our recurring revenue base. The Pharos transaction also provides a highly synergistic path to gain additional placements for our XTRAC excimer laser system.

We made upfront cash payments of $3.7 million in connection with the Pharos asset acquisition.

TheraClear Acquisition. In January 2022, the Company acquired certain assets related to the TheraClear devices from Theravant Corporation. The TheraClear asset acquisition will allow the Company to futher 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 Corporation 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, the Company also made a $0.5 million milestone payment upon the launch of the TheraClear Acne Therapy System, one of development related targets. Theravant Corporation 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.

MidCap Financing

In September 2021, we entered into an $8.0 million secured borrowing facility with MidCap Financial Trust, or MidCap. The facility bears interest at LIBOR plus 7.50%, with a LIBOR floor of 0.50%, and matures on September 1, 2026. In September 2022, we amended the facility to transition, upon the cessation of LIBOR, to one-month SOFR, or such other applicable period, plus 0.10%, with a floor or 0.50%. We are obligated to make interest-only payments through September 2024. From October 2024 to maturity, we will make payments of principal and interest 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 revenue thresholds. Upon an event of default, including a covenant violation, all principal and interest are due on demand.

Proceeds from our MidCap facility were used to repay, in their entirety, the outstanding principal and interest associated with our Economic Injury Disaster Loan. In September 2021, we also repaid our note payable with the proceeds from the pledged time deposit held by the lender.

Equity Distribution Agreement

In October 2021, we entered into an equity distribution agreement 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 3.0% 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 during fiscal 2022 or 2021.

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 have to 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 on Form 10-K for additional information regarding how we account for revenues.

Sales in the United States represented 66% and 77% of our total revenues for the years ended December 31, 2022 and 2021, 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 34% and 23% for the years ended December 31, 2022 and 2021, 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 2022 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 increase as we continue to execute on our growth initiatives and expand our business in both the United States and internationally.

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 2022 expenses.

Gain of Forgiveness of Debt

In fiscal 2021, we recognized a gain on forgiveness of debt associated with our Paycheck Protection Program ("PPP") loan.

Interest Expense

Interest expense consists of cash interest payable under our debt facilities 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 equivalent account balances.

Income Taxes

As of December 31, 2022, we had federal and state NOL carryforwards of $198.1 million and $60.8 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, 2022 and 2021

(in thousands)	**Year Ended December 31,**		**Change**	
	2022	**2021**	**Dollar**	**Percentage**
Revenues, net	$ 36,161	$ 29,977	$ 6,184	21%
Cost of revenues	14,393	10,127	4,266	42
Gross profit	21,768	19,850	1,918	10
Operating expenses:				
Engineering and product development	1,029	1,434	(405)	(28)
Selling and marketing	15,301	13,106	2,195	17
General and administrative	10,087	9,712	375	4
	26,417	24,252	2,165	9
Loss from operations	(4,649)	(4,402)	(247)	6
Other (expense) income:				
Interest expense	(926)	(314)	(612)	(195)
Interest income	89	15	74	493
Gain on forgiveness of debt	—	2,029	(2,029)	(100)
	(837)	1,730	(2,567)	(148)
Loss before income tax expense	$ (5,486)	$ (2,672)	$ (2,814)	105%

Revenues

Revenues by Geography

The following tables present revenues by geography for the periods presented below:

(in thousands)	Year Ended December 31,		Change	
	2022	2021	Dollar	Percentage
Domestic	$ 23,981	$ 23,197	$ 784	3%
International	12,180	6,780	5,400	80
Total Revenues	$ 36,161	$ 29,977	$ 6,184	21%

Revenues by Product Type

The following tables present revenues by segment for the periods presented below:

(in thousands)	Year Ended December 31,		Change	
	2022	2021	Dollar	Percentage
Dermatology recurring	$ 23,025	$ 22,528	$ 497	2%
Dermatology equipment	13,136	7,449	5,687	76
Total Revenues	$ 36,161	$ 29,977	$ 6,184	21%

Dermatology Recurring Procedures

The ongoing COVID-19 pandemic has had a negative impact on our results for 2022 and 2021, and we expect it will continue to have a negative impact on revenue given the change in the behavior of our customers and the ultimate consumer of our products and services as a result of the pandemic. Recognized treatment revenue for the year ended December 31, 2022 was $23.0 million, which we estimate is approximately 329,000 treatments with prices between $65 and $95 per treatment, compared to recognized treatment revenue for the year ended December 31, 2021 of $22.5 million, which is approximately 321,000 treatments with prices between $65 and $95 per treatment.

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. Therefore, our strategy is to continue to execute a 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. Furthermore, we increased our presence at trade shows throughout the United States during 2022, and we held our national sales meeting for the first time since the onset of the COVID-19 pandemic during the second quarter of 2022.

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, 2022 and 2021, we deferred domestic net revenues of $2.2 million and $1.9 million, respectively, which will be recognized as revenue over the remaining usage period for the related placements.

Dermatology Procedures Equipment

The ongoing COVID-19 pandemic has had a negative impact on our results for 2022 and 2021, and we expect it will continue to have a negative impact on revenue given the change in the behavior of our customers and the ultimate consumer of our products and services as a result of the pandemic. 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.

For the year ended December 31, 2021, dermatology procedures equipment revenues were $7.5 million. Internationally, we sold 38 systems (30 XTRAC and 8 VTRAC).

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

(in thousands)	**Year Ended December 31,**		**Change**	
	2022	**2021**	**Dollar**	**Percentage**
Revenues	$ 23,025	$ 22,528	$ 497	2%
Cost of revenues	8,371	6,418	1,953	30
Gross profit	$ 14,654	$ 16,110	$ (1,456)	(9)%
Gross profit percentage	63.6%	71.5%		

The primary reasons for the decrease in gross profit for the year ended December 31, 2022 were higher amortization of intangible assets due to the Pharos and TheraClear asset acquisitions and higher depreciation expenses and labor costs in 2022 compared to 2021, partially offset by higher recurring procedures sales.

Dermatology Procedures Equipment

(in thousands)	**Year Ended December 31,**		**Change**	
	2022	**2021**	**Dollar**	**Percentage**
Revenues	$ 13,136	$ 7,449	$ 5,687	76%
Cost of revenues	6,022	3,709	2,313	62
Gross profit	$ 7,114	$ 3,740	$ 3,374	90%
Gross profit percentage	54.2%	50.2%		

The primary reasons for the increase in gross profit for the year ended December 31, 2022 were a change in product mix resulting in greater sales of equipment with higher sales margins and recognition of deferred service revenue associated with assumed service contracts from Ra Medical, partially offset by higher amortization of intangible assets due to the Pharos and TheraClear asset acquisitions.

Engineering and Product Development

For the year ended December 31, 2022, engineering and product development expenses were $1.0 million as compared to $1.4 million for the year ended December 31, 2021. Engineering and product development costs during the year ended December 31, 2022 were lower primarily as a result of reduction of costs incurred in connection with developing XTRAC Momentum™ 1.0, our next generation excimer laser system that was commercially launched in February 2022.

Selling and Marketing

As of December 31, 2022, our sales and marketing personnel consisted of 63 full-time positions, 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, 2022, sales and marketing expenses were $15.3 million as compared to $13.1 million for the year ended December 31, 2021. Sales and marketing expenses for the year ended December 31, 2022 were higher, as compared to the same period in 2021, primarily due to investments we made in sales and marketing and direct-to-consumer and dermatologists advertising, as well as increased head count and employee-related expenses. Additionally, increased spending consisted of our national sales meeting and increased attendance at trade shows.

General and Administrative

For the year ended December 31, 2022, general and administrative expenses increased to $10.1 million from $9.7 million for the year ended December 31, 2021. General and administrative expenses were higher for the year ended December 31, 2022, as compared to the same period in 2021. The increase is primarily due to higher consulting services, including legal and professional services, offset by higher compensation, severance and recruiting expenses incurred during the first quarter of 2021 as a result of the CEO transition.

Gain on Forgiveness of Debt

During the year ended December 31, 2021, we received notification our PPP loan had been forgiven and we recorded a gain on forgiveness of debt of $2.0 million.

Interest Expense

Interest expense is primarily attributable to our debt obligations. For the year ended December 31, 2022, interest expense increased to $1.0 million from $0.3 million for the year ended December 31, 2021. The increase is primarily the result of a higher interest rate on the Senior Term Facility entered into in September 2021.

Interest Income

Interest income relates to the interest we receive on our cash, cash equivalents and restricted cash held with financial institutions.

Income Tax Expense

We recognized an income tax expense of $0.1 million for the year ended December 31, 2022 as compared to $34 thousand for the year ended December 31, 2021, which is comprised primarily of changes in 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 report is as follows:

(in thousands)	Year Ended December 31, 2022	2021
Gross Profit	$ 21,768	$ 19,850
Amortization of acquired intangible assets	2,031	570
Non-GAAP gross profit	$ 23,799	$ 20,420
Gross profit percentage	60.2%	66.2%
Non-GAAP gross profit percentage	65.8%	68.1%

(in thousands)	Year Ended December 31, 2022	2021
Net loss	$ (5,549)	$ (2,706)
Adjustments:		
Depreciation and amortization	5,293	3,736
Amortization of operating lease right-of-use asset	395	350
Loss on disposal of property and equipment	52	140
Income taxes	63	34
Gain on forgiveness of debt	—	(2,029)
Interest income	(89)	(15)
Interest expense	926	314
Non-GAAP EBITDA	1,091	(176)
Stock-based compensation	1,466	1,643
Non-GAAP adjusted EBITDA	$ 2,557	$ 1,467

Liquidity and Capital Resources

As of December 31, 2022, we had cash and cash equivalents and restricted cash of $6.8 million and an accumulated deficit of $227.2 million. We used $1.1 million in cash flows from operating activities and received cash flows from operating activities of $1.5 million during the years ended December 31, 2022 and 2021, 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, 2022, we had $8.0 million of borrowings outstanding under our debt facility with MidCap Financial Trust, or MidCap, which has a final maturity in September 2026.

In September 2021, we entered into an $8.0 million secured borrowing facility with MidCap. The facility bears interest at LIBOR plus 7.50%, with a LIBOR floor of 0.50%, and matures on September 1, 2026. In September 2022, we amended the facility to transition, upon the cessation of LIBOR, to one-month SOFR, or such other applicable period, plus 0.10%, with a floor or 0.50%. We are obligated to make interest-only payments through September 2024. From October 2024 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 revenue thresholds. Upon an event of default, including a covenant violation, all principal and interest are due on demand.

In October 2021, we entered into an equity distribution agreement 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 3.0% 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 during fiscal 2022 or 2021.

We cannot predict our revenues and expenses in the short term as a result of the COVID-19 pandemic 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 as of December 31, 2022 and anticipated revenues from sales of our products and operating expense management will be sufficient to meet our cash requirements for at least 12 months from the date of issuance of the 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:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Cash (used in) provided by		
Operating activities	$ (1,108)	$ 1,508
Investing activities	(4,183)	(7,126)
Financing activities	(500)	92
Net decrease in cash, cash equivalents and restricted cash	$ (5,791)	$ (5,526)

Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was $1.1 million for the year ended December 31, 2022, compared to cash, cash equivalents and restricted cash provided by operating activities of $1.5 million for the year ended December 31, 2021. The decrease in cash flows from operating activities for the year ended December 31, 2022 was primarily driven by an increase in inventories to avoid supply chain disruptions, an increase in accounts receivable, and a decrease in accrued compensation.

Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was $4.2 million for the year ended December 31, 2022, compared to cash, cash equivalents and restricted cash used in investing activities of $7.1 million for the year ended December 31, 2021. The decrease is primarily the result of the Pharos asset purchase in 2021, offset by the TheraClear asset purchase in 2022.

Financing Activities

During the year ended December 31, 2022, we received no proceeds and used $0.5 million in cash from financing activities for the payment of contingent consideration resulting from the TheraClear asset purchase. During the year ended December 31, 2021, we received net proceeds of $7.9 million from our senior term facility with MidCap, offset by debt repayments of $7.8 million associated with our note payable and EIDL Loan.

Contractual Obligations and Commitments

Debt Obligations

In September 2021, we entered into an $8.0 million secured borrowing facility with MidCap. The facility bears interest at LIBOR plus 7.50%, with a LIBOR floor of 0.50%, and matures on September 1, 2026. In September 2022, we amended the facility to transition, upon the cessation of LIBOR, to one-month SOFR, or such other applicable period, plus 0.10%, with a floor or 0.50%. We are obligated to make interest-only payments through September 2024. From October 2024 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 revenue thresholds. Upon an event of default, including a covenant violation, all principal and interest are due on demand.

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 four years. Remaining lease obligations are $1.1 million as of December 31, 2022, 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. As of December 31, 2022, we have estimated the future earnout payments at $8.6 million, of which $0.3 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 have not operated in a highly inflationary period, and we do not believe that inflation has had a material effect on our revenues or expenses. If we enter an inflationary period, it could have a material impact on our expenses.

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 on Form 10-K, 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.

Asset Acquisitions

Accounting for transactions as asset acquisitions is significantly different than business combinations. Goodwill is only recognized in business combination transactions. The fair value of contingent consideration is recognized in business combination transactions and may be recognized in asset acquisitions if payment is probable and the amount can be estimated. As a result, it is important to determine whether a business or an asset or a group of assets is acquired. A business is defined in ASC 805, *Business Combinations*, as an integrated set of inputs and processes that are capable of generating outputs that have the ability to provide a return to its investors or owners. Typical inputs include long-lived assets (including intangible assets or rights to use long-lived assets), intellectual property and the ability to obtain access to required resources. Typical processes include strategic, operational and resource management processes that are typically documented or evident through an organized workforce.

When substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the acquired set is not a business. We considered all of the above factors when determining whether a business was acquired. In evaluating our acquisition of TheraClear in 2022, we concluded that the fair value of consideration given to Theravant was concentrated in the acquired technology intangible. In evaluating our acquisition of Pharos in 2021, we concluded that the fair value of consideration given to Ra Medical was concentrated in the acquired customer list intangible. As such, we accounted for the transactions as asset acquisitions. The fair value was allocated to the acquired intangibles and is being amortized over their estimated useful lives.

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.

Goodwill and Intangible Impairments

As of December 31, 2022, we had $8.8 million of goodwill related to the acquisitions of 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. For both reporting units the fair value was in excess of the carrying value. Considerable management judgment is necessary to evaluate the impact of operating changes and to estimate future 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.

All of our intangibles are definite lived assets, with amortization recorded over the estimated useful life on a straight-line basis. As of December 31, 2022 we had $17.4 million of intangible assets. The definite 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

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. Several states have assessed the Company an aggregate of $2.4 million including penalties and interest for the period from March 2014 through April 2020. The Company received notification that an administrative state judge 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 $1.5 million of the total $2.4 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 State of New York Appeals Tribunal ("Tribunal") overturning the favorable sales tax determination of the administrative law judge. The Company filed an appeal of the Tribunal's decision, and posted the required appellate bond requiring posting cash collateral, with the New York State Appellate Division, and is awaiting for the appellate court to set a briefing and oral argument schedule.

The Company is also in another jurisdiction's administrative process of appeal with respect to the remaining $0.9 million of assessments, and the timing of the process has been impacted by the COVID-19 pandemic. 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.

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 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, 2022. 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, 2022.

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

None.

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 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

Our Board has adopted a written Code of Conduct applicable to all officers, directors and employees, which is available on our website (www.strataskinsciences.com) under "Corporate Governance" within the "Investors" section. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of this Code of Conduct by posting such information on the website address and location specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

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 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

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 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

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, 2022 and 2021, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years ended December 31, 2022 and 2021.

(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.

(b) Exhibits

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 Common Stock
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, 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 October 4, 2021)
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	Warrant Agreement to Purchase Shares of the Common Stock of STRATA Skin Sciences, Inc., dated as of September 30, 2021, between STRATA Skin Sciences, Inc. and MidCap Funding XXVII Trust. (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on October 4, 2021)
10.23	Registration Rights Agreement, dated as of September 30, 2021, 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 October 4, 2021)
10.24	Limited Consent and Amendment No. 1 to Credit and Security Agreement, between STRATA Skin Sciences, Inc. and MidCap Financial Trust as Agent for Lenders (incorporated by reference to Exhibit 10.84 to our Annual Report on Form 10-K for the year ended December 31, 2021).
10.25	Amendment No. 2 to Credit and Security Agreement, dated as of September 6, 2022, between STRATA Skin Sciences, Inc. and MidCap Financial Trust as Agent for Lenders (attached hereto).
10.26	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)
10.27	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)
10.28	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)
10.29*	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)
10.30*	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)
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 31, 2023

By: /s/ Robert J. Moccia
Robert J. Moccia
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:

Signature	Title	Date
/s/ Robert J. Moccia Robert J. Moccia	President, Chief Executive Officer, and Director (*Principal Executive Officer)*	March 31, 2023
/s/ Christopher Lesovitz Christopher Lesovitz	Chief Financial Officer (*Principal Financial Officer and Financial Officer*)	March 31, 2023
/s/ William D. Humphries William D. Humphries	Director and Chairperson of the Board of Directors	March 31, 2023
/s/ Uri Geiger Uri Geiger	Director	March 31, 2023
/s/ Samuel Rubinstein Samuel Rubinstein	Director	March 31, 2023
/s/ Nachum Shamir Nachum Shamir	Director	March 31, 2023
/s/ Douglas Strang Douglas Strang	Director	March 31, 2023
/s/ Patricia Walker Patricia Walker	Director	March 31, 2023

STRATA SKIN SCIENCES, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022 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 12 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 currently 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, 2022.

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, control premium and market capitalization reconciliation.

Intangible asset acquisition:

As discussed in Note 3 to the consolidated financial statements, in January 2022, 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 Company determined this transaction represented an asset acquisition as substantially all of the value was being ascribed to one intangible asset as defined by ASC 805, *Business Combinations* ("ASC 805"). The contingent consideration is accounted for as a contingent liability under ASC 450, *Contingencies*.

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

- The determination of the fair value of the intangible asset and 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 valuation of the acquired intangible asset and contingent consideration included the following:

- We evaluated management's determinations of the assets acquired, liabilities assumed and the consideration paid under the asset purchase agreement for reasonableness.
- We evaluated management's significant accounting policies related to accounting for asset acquisitions, intangible assets and 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.
- We tested the existence, completeness and valuation of the tangible assets acquired and liabilities assumed, to assess the consideration paid reconciliation.

/s/ Marcum LLP

Marcum LLP

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

Philadelphia, Pennsylvania
March 31, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 5,434	$ 12,586
Restricted cash	1,361	—
Accounts receivable, net of allowance for doubtful accounts of $382 and $275 at December 31, 2022 and 2021, respectively	4,471	3,433
Inventories	5,547	3,489
Prepaid expenses and other current assets	691	462
Total current assets	17,504	19,970
Property and equipment, net	7,498	6,883
Operating lease right-of-use assets	975	638
Intangible assets, net	17,394	10,083
Goodwill	8,803	8,803
Other assets	98	216
Total assets	$ 52,272	$ 46,593
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,425	$ 2,822
Accrued expenses and other current liabilities	6,555	6,377
Deferred revenues	2,778	3,285
Current portion of operating lease liabilities	355	318
Current portion of contingent consideration	313	—
Total current liabilities	13,426	12,802
Long-term debt, net	7,476	7,319
Deferred revenues and other liabilities	314	400
Deferred tax liability	306	266
Operating lease liabilities, net of current portion	610	392
Contingent consideration, net of current portion	8,309	—
Total liabilities	30,441	21,179
Commitments and contingencies (Note 12)		
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; 34,723,046 and 34,364,679 shares issued and outstanding at December 31, 2022 and 2021, respectively	35	34
Additional paid-in capital	249,024	247,059
Accumulated deficit	(227,228)	(221,679)
Total stockholders' equity	21,831	25,414
Total liabilities and stockholders' equity	$ 52,272	$ 46,593

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,	
	2022	**2021**
Revenues, net	$ 36,161	$ 29,977
Cost of revenues	14,393	10,127
Gross profit	21,768	19,850
Operating expenses:		
Engineering and product development	1,029	1,434
Selling and marketing	15,301	13,106
General and administrative	10,087	9,712
	26,417	24,252
Loss from operations	(4,649)	(4,402)
Other (expense) income:		
Interest expense	(926)	(314)
Interest income	89	15
Gain on forgiveness of debt	—	2,029
	(837)	1,730
Loss before income tax expense	(5,486)	(2,672)
Income tax expense	(63)	(34)
Net loss	$ (5,549)	$ (2,706)
Net loss per share of common stock, basic and diluted	$ (0.16)	$ (0.08)
Weighted average shares of common stock outstanding, basic and diluted	34,712,246	34,050,274

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 Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2021	33,801,045	$ 34	$ 244,831	$ (218,973)	$ 25,892
Stock-based compensation expense	—	—	1,643	—	1,643
Exercise of stock options	329,076	—	—	—	—
Issuance of restricted stock	234,558	—	—	—	—
Issuance of common stock warrants in connection with Senior Term Facility	—	—	585	—	585
Net loss	—	—	—	(2,706)	(2,706)
Balance at December 31, 2021	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	34,723,046	$ 35	$ 249,024	$ (227,228)	$ 21,831

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,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (5,549)	$ (2,706)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	5,293	3,736
Amortization of operating lease right-of-use assets	395	350
Amortization of deferred financing costs and debt discount	157	37
Provision for doubtful accounts	107	1
Stock-based compensation	1,466	1,643
Loss on disposal of property and equipment	52	140
Gain on forgiveness of debt	—	(2,029)
Deferred taxes	40	12
Changes in operating assets and liabilities:		
Accounts receivable	(1,145)	(490)
Inventories	(1,524)	(45)
Prepaid expenses and other assets	(111)	(65)
Accounts payable	603	58
Accrued expenses and other liabilities	229	1,679
Deferred revenues	(644)	(444)
Operating lease liabilities	(477)	(369)
Net cash (used in) provided by operating activities	(1,108)	1,508
Cash flows from investing activities:		
Purchase of property and equipment	(3,552)	(3,653)
Cash paid in connection with TheraClear asset acquisition	(631)	—
Cash paid in connection with Ra Medical asset acquisition	—	(3,473)
Net cash used in investing activities	(4,183)	(7,126)
Cash flows from financing activities:		
Payment of contingent consideration	(500)	—
Proceeds from long-term debt	—	8,000
Payment of deferred financing costs	—	(133)
Repayment of note payable	—	(7,275)
Repayment of long-term debt	—	(500)
Net cash (used in) provided by financing activities	(500)	92
Net decrease in cash, cash equivalents and restricted cash	(5,791)	(5,526)
Cash, cash equivalents and restricted cash at beginning of year	12,586	18,112
Cash, cash equivalents and restricted cash at end of year	$ 6,795	$ 12,586
Supplemental disclosure of cash flow information:		
Cash paid during the year for interest	$ 744	$ 222
Cash paid during the year for income taxes	$ 19	$ —
Supplemental schedule of non-cash investing and financing activities:		
Change in operating lease right-of-use assets and liabilities due to new and amended leases	$ 732	$ —
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 acquisition	$ 9,122	$ —
Common stock issued in connection with TheraClear asset acquisition	$ 500	$ —
Transfer of property and equipment to inventories	$ 463	$ —
Issuance of common stock warrants in connection with Senior Term Facility	$ —	$ 585
Assumed deferred revenues in connection with asset acquisition	$ —	$ 1,841

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.

COVID-19 Pandemic

In late 2019, there was an outbreak of a new strain of coronavirus ("COVID-19") which became a global pandemic. While many of COVID-19's initial disruptions and damage to the global economy have been mitigated, the COVID-19 pandemic has continued to negatively impact the economy, 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, and the impact of the ongoing COVID-19 pandemic and its variants on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frames, will depend on future developments, including, but not limited to, the ongoing mutations and spread of the COVID-19 virus, impact on business operations, supply chains and transport, and governmental and societal responses thereto, all of which are uncertain and cannot be predicted.

The ongoing COVID-19 pandemic has had a negative impact on the Company's results of operations and financial performance through fiscal 2022, and the Company expects it will continue to have a negative impact on revenues, earnings and cash flows until such time as its customers adjust to the pandemic's ramifications. Some physician offices continue to experience staffing issues, and the Company believes these shortages of trained personnel have negatively impacted its business. Accordingly, current results and financial conditions discussed herein may not be indicative of future operating results and trends.

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. Historically, Ukraine has 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 supporters have been resourceful in continuing to supply gases to the Company but cannot assure it that the supply will not remain uninterrupted. The reduced supply and war have raised the price of gas significantly 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 disruptions caused by this war.

Liquidity and Going Concern

The Company has been negatively impacted by the ongoing 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, was required to restrict cash for potential sales tax liabilities (see Notes 2 and 12) and refinanced its debt at a lower interest rate. 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. 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 ongoing COVID-19 pandemic and the Russia-Ukraine War on the financial markets, supply chain disruptions and rising interest rates, could interfere with the Company's ability to access financing and on favorable terms.

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, 2022 and 2021.

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, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and reported amounts of revenue and expenses during the reporting period. The Company's significant estimates and judgments involve 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 acquired intangible assets and 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 two customers and one customer, international distributors, from which it earns dermatology recurring procedures and dermatology procedures equipment revenues, that accounted for more than 10% of the Company's revenues for the years ended December 31, 2022 and 2021, respectively. Revenues from these customers were $8.5 million and $3.4 million, or 23% and 11%, of total net revenues during the years ended December 31, 2022 and 2021, respectively. Accounts receivable associated with these customers was $0.5 million and 11% of net accounts receivable as of December 31, 2022, and less than 10% of total accounts receivable as of December 31, 2021. No other customer represented more than 10% of total accounts receivable as of December 31, 2022 or 2021.

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, 2022 and 2021, cash equivalents consisted of credit card transactions with settlement terms of less than five days.

Restricted Cash

As discussed more fully in Note 12, 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 filed an appeal of the Tribunal's decision, and posted the required appellate bond requiring the posting of cash collateral, with the New York State Appellate Division, and is awaiting for the appellate court to set a briefing and oral argument schedule. The cash collateral is recorded as restricted cash on the consolidated balance sheet as of December 31, 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,	
	2022	2021
Cash and cash equivalents	$ 5,434	$ 12,586
Restricted cash	1,361	—
Total cash, cash equivalents and restricted cash presented in the consolidated statements of cash flows	$ 6,795	$ 12,586

Accounts Receivable and Allowance for Doubtful Accounts

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 potential credit losses. The Company does not require collateral or other security for accounts receivable. The Company maintains allowances for doubtful accounts 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, whether for sale or for placement, is accumulated in inventory.

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. 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.

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 to the extent that the implied fair value of the reporting unit's goodwill is less than the carrying value of the reporting unit's goodwill. The Company bypassed the qualitative assessment and did a quantitative assessment by comparing the fair value of a reporting unit with its carrying amount. The Company's annual goodwill impairment test resulted in no impairment charges during the years ended December 31, 2022 and 2021.

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, 2022 and 2021.

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 to 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, 2022 and 2021 is summarized as follows (in thousands):

	December 31,	
	2022	2021
Balance, beginning of year	$ 79	$ 113
Additions	246	71
Expirations and claims satisfied	(118)	(105)
Total	207	79
Less current portion within accrued expenses and other current liabilities	(136)	(59)
Balance within deferred revenues and other liabilities	$ 71	$ 20

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 period 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.

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,	
	2022	2021
Dermatology recurring procedures	$ 23,025	$ 22,528
Dermatology procedures equipment	13,136	7,449
Total net revenues	$ 36,161	$ 29,977

The following table summarizes the Company's expected future undiscounted fixed treatment code payments from dermatology recurring procedures (in thousands):

Years ending December 31:	
2023	$ 1,207
2024	975
2025	384
2026	166
2027	4
	$ 2,736

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, 2022 and 2021, the aggregate amount of the transaction price allocated to remaining performance obligations was $0.6 million and $1.3 million, respectively, and the Company expects to recognize $0.4 million and $0.9 million, respectively, of the remaining performance obligations within one year and the remainder over one to three years. The decrease in remaining performance obligations from December 31, 2021 to December 31, 2022 is due to the recognition of deferred service revenue associated with assumed service contracts from Ra Medical (see Note 3). 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 stand-alone 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, 2022 and 2021, the $0.4 million and $0.9 million of short-term contract liabilities, respectively, is presented as deferred revenues and the $0.2 million and $0.4 million of long-term contract liabilities, respectively, is presented within deferred revenues and other liabilities on the consolidated balance sheets, respectively. For the years ended December 31, 2022 and 2021, the Company recognized $0.9 million and $0.1 million, respectively, as revenue from amounts classified as contract liabilities (i.e. deferred revenues) as of December 31, 2021 and 2020.

With respect to contract acquisition costs, the Company applied 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 $1.6 million during each of the years ended December 31, 2022 and 2021.

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.

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, 2022. 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 2019 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,	
	2022	2021
Restricted stock units	278,004	90,540
Stock options	4,474,714	3,938,613
Common stock warrants	373,626	373,626
	5,126,344	4,402,779

Accounting Pronouncements Recently Adopted

In May 2021, the FASB issued ASU 2021-04, *Earnings per Share (Topic 260), Debt – Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges or Freestanding Equity-Classified Written Call Options*. The pronouncement outlines how an entity should account for modifications made to equity-classified written call options, including stock options and warrants to purchase the entity's own common stock. The guidance in the ASU requires an entity to treat a modification of an equity-classified written call option that does not cause the option to become liability-classified as an exchange of the original option for a new option. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the equity-classified written call option or as termination of the original option and issuance of a new option. The guidance is effective prospectively for fiscal years beginning after December 15, 2021 and early adoption is permitted. The adoption of this guidance on January 1, 2022 did not have a material effect on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet 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 is currently used. The standard also establishes additional disclosures related to credit risks. This standard is effective for fiscal years beginning after December 15, 2022 and early adoption is permitted. The Company does not believe this will have a material effect on its consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* and in January 2021, the FASB issued ASU 2021-01, Reference Rate Reform (Topic 848): Scope. These pronouncements provide temporary optional expedients and exceptions for applying GAAP principles to contract modifications and hedging relationships to ease the financial reporting burdens of the expected market transition from LIBOR and other interbank offered rates to alternative reference rates. In December 2022, the FASB issued ASU 2022-06, Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848, which allows Topic 848 to be adopted and applied prospectively to contract modifications made on or before December 31, 2024. The Company continues to evaluate the temporary expedients and options available under this guidance and the effects of these pronouncements and, as the Company does not have any hedging activities, does not believe this will have a material effect on its consolidated financial statements.

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 on 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 fiscal years beginning after December 15, 2023 and early adoption is permitted. The Company does not currently engage in contracts covered by this guidance and does not believe it will have a material effect on the Company's consolidated financial statements, but it could in the future.

3. Acquisitions

TheraClear Asset Acquisition

In January 2022, the Company acquired certain assets related to the TheraClear devices from Theravant Corporation ("Theravant"). The TheraClear asset acquisition will allow 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, 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.

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* ("ASC 805").

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	$	10,253
Assets acquired:		
Technology intangible asset	$	10,182
Inventories		71
Total assets acquired	$	10,253

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, which consists of $0.3 million as of December 31, 2022, is classified as current on the consolidated balance sheet.

Pharos Asset Acquisition

In August 2021, the Company acquired certain assets and liabilities related to the U.S. dermatology Pharos business from Ra Medical Systems, Inc. ("Ra Medical"). Ra Medical's Pharos excimer laser system holds FDA clearance to treat chronic skin diseases, including psoriasis, vitiligo, atopic dermatitis and leukoderma. The acquisition of these assets and liabilities allows the Company to market its full business solutions to Ra Medical's existing customer base comprised of 400 dermatology practices offering opportunities to increase its recurring revenue base and a pathway to gain additional placements for the Company's XTRAC excimer laser system.

The purchase price of $3.7 million was paid in cash at the time of acquisition. In addition, the Company assumed certain extended warranty service contracts associated with acquired laser system products. Concurrent with the purchase of the net assets, the Company and Ra Medical entered into a services agreement whereby Ra Medical will provide certain transitional services for the Company as it integrates the acquired assets into the Company. The Company determined this transaction represented an asset acquisition as substantially all of the value was in the acquired customer list intangible asset as defined by ASC 805.

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

Consideration:		
Cash payment	$	3,700
Transaction costs		57
Total consideration	$	3,757
Assets acquired:		
Inventories	$	284
Customer lists intangible asset		5,314
Total assets acquired		5,598
Liabilities assumed:		
Deferred revenues – service contracts		1,841
Total liabilities assumed		1,841
Net assets acquired	$	3,757

The customer lists intangible asset is being amortized on a straight-line basis over a period of 12 years. As the transaction was accounted for as an asset acquisition, the Company allocated consideration paid to the inventories acquired and the deferred revenues assumed, with the remaining consideration paid allocated to the customer lists intangible asset, which also equals its estimated fair value. The intangible asset was valued using an excess earnings model. Significant assumptions used in the excess earnings model include estimated customer sales growth, customer attrition and weighted average cost of capital of 3%, 5% and 17%, respectively.

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, 2022 and 2021 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, 2022 and 2021 due to its variable interest rate.

5. Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2022	2021
Raw materials and work-in-process	$ 5, 418	$ 3,201
Finished goods	129	288
	$ 5,547	$ 3,489

6. Property and Equipment, net

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

	December 31,	
	2022	2021
Lasers placed-in-service	$ 28,790	$ 25,949
Equipment, computer hardware and software	293	238
Furniture and fixtures	235	213
Leasehold improvements	136	254
	29,454	26,654
Less: accumulated depreciation and amortization	(21,956)	(19,771)
	$ 7,498	$ 6,883

The Company recorded depreciation and amortization expense of $2.4 million and $2.1 million during the years ended December 31, 2022 and 2021, 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 four 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, 2021.

Operating lease costs were $0.4 million for each of the years ended December 31, 2022 and 2021. Cash paid for amounts included in the measurement of operating lease liabilities was $0.4 million and $0.5 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, the weighted average incremental borrowing rate was 8.76% and 9.76%, respectively, and the weighted average remaining lease term was 2.8 years and 2.3 years, respectively.

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

The following table summarizes the Company's operating lease maturities as of December 31, 2022 (in thousands):

Years ending December 31:	
2023	$ 426
2024	386
2025	195
2026	81
Total remaining lease payments	1,088
Less: imputed interest	(123)
Total lease liabilities	$ 965

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):

December 31, 2022	Balance	Accumulated Amortization	Net Book Value
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
	$ 31,596	$ (14,202)	$ 17,394

December 31, 2021	Balance	Accumulated Amortization	Net Book Value
Core technology	$ 5,700	$ (3,705)	$ 1,995
Product technology	2,000	(2,000)	—
Customer relationships	6,900	(4,485)	2,415
Tradenames	1,500	(975)	525
Pharos customer lists	5,314	(166)	5,148
	$ 21,414	$ (11,331)	$ 10,083

The Company recorded amortization expense of $2.9 million and $1.6 million during the years ended December 31, 2022 and 2021, respectively.

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:	
2023	$ 2,871
2024	2,871
2025	2,166
2026	1,461
2027	1,461

Goodwill consists of the following (in thousands):

	December 31,	
	2022	2021
Dermatology recurring procedures segment	$ 7,958	$ 7,958
Dermatology procedures equipment segment	845	845
	$ 8,803	$ 8,803

9. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2022	2021
Warranty obligations	$ 136	$ 59
Compensation and related benefits	1,997	2,052
State sales, use and other taxes	3,986	3,697
Professional fees and other	436	569
	$ 6,555	$ 6,377

10. Note Payable

In December 2020, the Company had renewed its $7.3 million loan with a commercial bank pursuant to a one-year Fixed Rate – Term Promissory Note (the "Note"). The Company's obligations under the Note were secured by an Assignment and Pledge of Time Deposit ("Time Deposit"), under which the Company had pledged to the commercial bank the proceeds of a time deposit account in the amount of the loan and recorded the time deposit and accrued interest as restricted cash on the balance sheet. The principal was due on December 30, 2021 with no penalties for prepayments. The interest rate was fixed at 1.40%. The secured time deposit had a fixed interest rate of 0.40%. The Company repaid the Note with the proceeds from the Time Deposit in September 2021.

11. Long-Term Debt

Senior Term Facility

On September 30, 2021, the Company entered into a credit and security agreement with MidCap Financial Trust, also acting as the administrative agent, and the lenders identified therein ("Senior Term Facility"). The Senior Term Facility provides for an $8.0 million senior term loan that was drawn upon by the Company upon executing the agreement. On September 30, 2021, the Company also repaid the outstanding principal and interest for its Note (Note 10) and the Economic Injury Disaster Loan. Borrowings under the Senior Term Facility bear interest at LIBOR (with a LIBOR floor rate of 0.50%) plus 7.50% per year and mature on September 1, 2026, unless terminated earlier. The interest rate was 11.72% and 8.00% as of December 31, 2022 and 2021, respectively. The Company is obligated to make monthly interest-only payments through September 30, 2024. From October 1, 2024 to the date of maturity, the Company will make 24 equal monthly principal payments plus interest, and all borrowings are secured by substantially all of the Company's assets. The Senior Debt Facility was amended on January 10, 2022 to provide MidCap Financial Trust's consent to the acquisition of TheraClear (Note 3). In September 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 or 0.50%.

The Company may voluntarily prepay the outstanding term loan, with such prepayment 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) 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 September 30, 2021, (ii) 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 September 30, 2021, or (iii) 1.00% of the outstanding principal prepaid or required to be prepaid (whichever is greater), if the prepayment is made after 36 months after September 30, 2021 and prior to the maturity date.

The Senior Term Facility contains certain customary representations and warranties, affirmative covenants and conditions. The Senior Term Facility also contains a number of negative covenants that subject the Company to certain exceptions and waivers and restrictions, as defined in the agreement. In addition, the Senior Term Facility contains a quarterly financial covenant that requires the Company to have a specified minimum amount of net revenue for the trailing 12-month period, with compliance measured on the last day of each fiscal quarter beginning on September 30, 2021. At December 31, 2022, the minimum net revenue threshold was $28.0 million. The minimum net revenue threshold will increase to $30.0 million by December 31, 2023. At December 31, 2022, the Company was in compliance with all financial covenants within the Senior Term Facility.

The Senior Term Facility contains customary indemnification obligations and customary events of default, including, among other things, (i) nonpayment, (ii) breach of warranty, (iii) nonperformance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (vi) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) regulatory matters, (x) failure to remain a publicly traded company, and (xi) material adverse event. Where an event of default arises from certain bankruptcy events, the commitments shall automatically and immediately terminate and the principal of, and interest then outstanding on, all of the loans shall become immediately due and payable. Subject to certain notice requirements and other conditions, upon the occurrence of other events of default, including the occurrence of a condition having or reasonably likely to have a material adverse effect, commitments may be terminated and the principal of, and interest then outstanding on, all of the loans may become immediately due and payable. At December 31, 2022, no event of default had occurred and 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.

In connection with entering into the Senior Term Facility, the Company issued an affiliate of the lender 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 is equity classified and is exercisable at any time on or prior to the tenth anniversary of its issue date. The estimated fair value of the warrants was $0.6 million and determined using the Black-Scholes option pricing model. The key assumptions used in the Black-Scholes option pricing model were (i) an expected term of ten years, (ii) expected volatility of 88.6%, (iii) a risk-free rate of 1.50% and (iv) no estimated dividend yield. In addition, the Company incurred third party costs and lender fees of $0.1 million. The proceeds were allocated on a basis that approximates the relative fair value method. The fair value of the warrants and fees incurred were recorded as a debt discount and are being recognized as interest expense over the life of the Senior Term Facility using the effective-interest method. The unamortized debt discount was $0.5 million and $0.7 million as of December 31, 2022 and 2021, respectively. 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. The Company recognized interest expense of $0.3 million during the year ended December 31, 2021, of which $37 thousand was related to the amortization of the debt discount.

Future minimum principal payments at December 31, 2022 are as follows (in thousands):

Years ending December 31:	
2024	$ 1,000
2025	4,000
2026	3,000
	$ 8,000

Paycheck Protection Program Loan

On April 22, 2020, the Company closed a loan of $2.0 million (the "PPP Loan") from a commercial bank, pursuant to the Paycheck Protection Program ("PPP") administered by the Small Business Administration (the "SBA") pursuant to the CARES Act. The PPP Loan would have matured on May 1, 2022 and bore an interest rate of 1% per year. Payments of principal and interest of any unforgiven balance were scheduled to commence December 1, 2020, but were deferred until the SBA approved of the forgiveness amount. In the second quarter of 2021, the Company received notification that the PPP Loan had been forgiven. Accordingly, the Company recorded a gain on forgiveness of debt in the amount of the loan of $2.0 million.

Economic Injury Disaster Loan

On May 22, 2020, the Company secured the EIDL Loan from the SBA under its Economic Injury Disaster Loan ("EIDL") assistance program in light of the impact of the COVID-19 pandemic on the Company's business. The principal amount of the EIDL Loan was up to $0.5 million, with proceeds to be used for working capital purposes, and was collateralized by all the Company's assets. On June 12, 2020, the Company received these funds from the SBA. Interest accrued at the rate of 3.75% per year. Installment payments, including principal and interest, were originally due monthly beginning March 26, 2021 (12 months from the date of the promissory note) in the amount of $2 thousand. In March 2021, the SBA deferred payments on the EIDL loans by an additional 12 months. The balance of principal and interest was payable over the next 30 years from the date of the promissory note. There were no penalties for prepayment. Based upon guidance issued by the SBA on June 19, 2020, the EIDL Loan was not required to be refinanced by the PPP Loan. On September 30, 2021, the Company repaid this loan in full.

12. 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 ("Co-Defendant") 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 would require the Company to pay $0.1 million, is tentative and subject to court approval and the right of individual class members to reject the settlement and proceed on their own. As of December 31, 2022, $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 revenues. The Company's sales tax expense that is not presently being collected and remitted for the recurring revenues 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. Several states have assessed the Company an aggregate of $2.4 million including penalties and interest for the period from March 2014 through April 2020. The Company received notification that an administrative state judge 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 $1.5 million of the total $2.4 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 State of New York Tax Appeals Tribunal ("Tribunal") overturning the favorable sales tax determination of the administrative law judge. The Company filed an appeal of the Tribunal's decision, and posted the required appellate bond requiring posting cash collateral, with the New York State Appellate Division, and is awaiting for the appellate court to set a briefing and oral argument schedule.

The Company is also in another jurisdiction's administrative process of appeal with respect to the remaining $0.9 million of assessments, and the timing of the process has been impacted by the COVID-19 pandemic. 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 percentage of the employee's contribution. For each of the years ended December 31, 2022 and 2021, the Company's contributions to the plan were $0.3 million.

Milestone Payments

In January 2022, the Company entered into a Development Agreement (the "Development Agreement") with Theravant Corporation ("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.

13. 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, 2022 and 2021.

Common Stock

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

The Company issued 329,076 shares upon the exercise of options and 234,558 shares upon the vesting of restricted stock during the year ended December 31, 2021.

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 2022 or 2021**.**

Common Stock Warrants

In September 2021 and in connection with entering into the Company's Senior Term Facility (Note 11), 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 is equity classified and is exercisable at any time on or prior to the tenth anniversary of its issue date. As of December 31, 2022, the warrant remains outstanding in its entirety.

14. 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, 2022, there were 3,193,706 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 of $1.3 million and $1.6 million (for all awards and modifications, if any) for the years ended December 31, 2022 and 2021, respectively, within general and administrative expenses in the accompanying consolidated statements of operations. During the year ended December 31, 2022, the Company also recorded share-based compensation expense of $0.2 million within selling and marketing expenses in the accompanying consolidated statement of operations.

On March 30, 2022, the Company granted 160,000 stock-based options to the Chief Executive Officer. The vesting of these awards is 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. As of December 31, 2022, the market condition was not met and 60,000 of the stock-based options were forfeited.

In connection with the separation of the Company's Chief Executive Officer in February 2021, the Company accelerated the vesting of all unvested options to purchase shares of common stock and extended the period to exercise to August 22, 2021. This acceleration and the extension of the period to vest met the modification criteria for accounting purposes. For these modifications, the Company calculated and recorded additional compensation expense of $0.2 million.

Stock Options

The following table summarizes stock option activity for the years ended December 31, 2022 and 2021:

	Number of Shares under Option Plan	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (in years)
Outstanding at January 1, 2021	5,292,888	$ 1.87	
Granted	2,463,714	1.70	
Exercised	(1,557,628)	1.12	
Forfeited and expired	(2,260,361)	2.10	
Outstanding at December 31, 2021	3,938,613	$ 1.90	7.91
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
Exercisable at December 31, 2022	2,202,792	$ 1.88	7.28

The weighted-average grant date fair value of options granted was $1.06 and $1.27 per share during the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the total unrecognized compensation expense related to unvested stock option awards was $2.3 million, which the Company expects to recognize over a weighted-average period of approximately 2.2 years. 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 aggregate intrinsic value of options outstanding and options exercisable at December 31, 2021 was $26 thousand and $4 thousand, respectively, and the aggregate intrinsic value of options that were exercised during the year ended December 31, 2021 was $0.5 million.

During the year ended December 31, 2021, there were 1,557,628 options that were exercised on a cashless basis at $1.12 per share resulting in the net issuance of 329,076 shares of common stock.

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, 2022 and 2021 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 ordinary shares.

For the years ended December 31, 2022 and 2021, 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,	
	2022	2021
Expected term (in years)	6.10	5.96
Expected volatility	89.57%	90.03%
Risk-free rate	2.51%	1.08%
Dividend rate	0.00%	0.00%

Restricted Stock Units

Restricted stock units have been issued to certain board members. Restricted stock units unvested are summarized in the following table:

	Number of Units	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2021	—	$ —
Granted	290,861	1.44
Vested	(146,364)	1.42
Forfeited and expired	(53,957)	1.45
Unvested at December 31, 2021	90,540	$ 1.45
Granted	187,464	0.96
Vested	(158,407)	1.26
Forfeited and expired	—	—
Unvested at December 31, 2022	119,597	$ 0.93

As of December 31, 2022, the total unrecognized compensation expense related to unvested restricted stock units was less than $0.1 million, which the Company expects to recognize over a weighted-average period of approximately 0.5 years. During the first quarter of 2023, the Company issued 158,407 shares of common stock related to the restricted stock units that vested during 2022.

15. Income Taxes

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

	Year Ended December 31,	
	2022	2021
Current:		
Federal	$ —	$ —
State	23	22
	23	22
Deferred:		
Federal	23	23
State	17	(11)
	40	12
Income tax expense	$ 63	$ 34

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.

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

	December 31,	
Deferred tax assets (liabilities)	**2022**	**2021**
Net operating loss carryforwards	$ 45,077	$ 46,596
Intangible assets	1,697	1,039
Inventory	57	26
Reserves and accrued expenses	1,431	1,230
Property and equipment	1,111	441
Stock-based compensation	548	458
Operating lease right-of-use assets	(242)	(159)
Goodwill	(1,095)	(950)
Operating lease liabilities	240	177
481(a) adjustment	(333)	(667)
Interest expense limitation carryover	208	—
Less: valuation allowance	(49,005)	(48,457)
Net deferred tax liability	$ (306)	$ (266)

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 the 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, 2022 and 2021. The valuation allowance increased by $0.5 million and $0.1 million during the years ended December 31, 2022 and 2021, respectively. The Company does not have unrecognized tax benefits as of December 31, 2022 or 2021. 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,	
	2022	**2021**
Federal	$ 198,144	$ 204,314
State	$ 60,784	$ 60,654

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.

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:

	December 31,	
	2022	2021
Federal tax expense at statutory rate	21.00%	21.00%
State tax, net of federal benefit	(0.58)%	(0.33)%
Permanent differences	(2.23)%	8.90%
Other difference and true ups	(11.20)%	(25.27)%
Change in valuation allowance	(8.14)%	(5.57)%
Tax provision	(1.15)%	(1.27)%

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 Company is currently evaluating the various provisions of the IRA and does not anticipate a material impact on its consolidated financial statements.

16. 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.

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, 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
	14,175	2,155	26,417
Income (loss) from operations	479	4,959	(4,649)
Interest expense	—	—	(926)
Interest income	—	—	89
Income (loss) before income tax expense	$ 479	$ 4,959	$ (5,486)

Year Ended December 31, 2021	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Total
Revenues	$ 22,528	$ 7,449	$ 29,977
Cost of revenues	6,418	3,709	10,127
Gross profit	16,110	3,740	19,850
Gross profit %	71.5%	50.2%	66.2%
Allocated expenses:			
Engineering and product development	1,251	183	1,434
Selling and marketing	12,257	849	13,106
Unallocated expenses	—	—	9,712
	13,508	1,032	24,252
Income (loss) from operations	2,602	2,708	(4,402)
Interest expense	—	—	(314)
Interest income	—	—	15
Gain on debt extinguishment	—	—	2,029
Income (loss) before income tax expense	$ 2,602	$ 2,708	$ (2,672)

For the years ended December 31, 2022 and 2021, depreciation and amortization by reportable segment were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Dermatology recurring procedures	$ 4,421	$ 3,334
Dermatology procedures equipment	857	384
Unallocated expenses	15	18
Consolidated total	$ 5,293	$ 3,736

The following tables present the Company's revenue disaggregated by geographical region for the years ended December 31, 2022 and 2021 (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, 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	$ 23,025	$ 13,136	$ 36,161

Year Ended December 31, 2021	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Total
Domestic	$ 21,215	$ 1,982	$ 23,197
China	—	931	931
Korea	941	2,412	3,353
Other foreign	372	2,124	2,496
Total	$ 22,528	$ 7,449	$ 29,977

As of December 31, 2022 and 2021, total assets by reportable segment were as follows (in thousands):

	December 31,	
	2022	2021
Dermatology recurring procedures	$ 37,230	$ 30,897
Dermatology procedures equipment	7,890	2,662
Other unallocated assets	7,152	13,034
Consolidated total	$ 52,272	$ 46,593

Long-lived assets of $0.6 million and $1.0 million were located in international markets, primarily Korea and Japan, as of December 31, 2022 and 2021, respectively, with the remainder located in domestic markets.

17. Subsequent Events

On October 26, 2022, 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 February 27, 2023, the Company received written notice from Nasdaq that it had regained compliance with the listing requirements with respect to its minimum bid price, and the Company will continue to trade on Nasdaq.

Exhibit 10.25

Execution Version

AMENDMENT NO. 2 TO CREDIT AND SECURITY AGREEMENT

This AMENDMENT NO. 2 TO CREDIT AND SECURITY AGREEMENT (this "**Agreement**") is made as of this 6th day of September, 2022 ("**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, 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. Borrowers have requested, and Agent and Lenders have agreed, to amend certain provisions of the Existing Credit 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**. Subject to the terms and conditions of this Agreement, including, without limitation, the conditions to effectiveness set forth in Section 3 below, the Existing Credit Agreement is hereby amended as follows, which amendments to the Existing Credit Agreement are effective as of the first day after the end of the Applicable Interest Period during which this Agreement becomes effective in accordance with Section 3 below:

(a) Section 2.6(a) of the Existing Credit Agreement is hereby amended by:

(i) renumbering the existing Section 2.6(a) as Section 2.6(a)(i); and

(ii) adding the following new clauses (ii) and (iii) thereto:

"(ii) In the event one or more of the following events occurs with respect to Term SOFR: (a) a public statement or publication of information by or on behalf of the SOFR Administrator announcing that the SOFR Administrator has ceased or will cease to provide Term SOFR for a 1-month period, permanently or indefinitely, *provided* that, at the time of such statement or publication, there is no successor administrator that will continue to provide Term SOFR for a 1-month period; (b) a public statement or publication of information by the regulatory supervisor for the SOFR Administrator, the Federal Reserve Board, the Federal Reserve Bank of New York, an insolvency official or resolution authority with jurisdiction over the SOFR Administrator, or a court or an entity with similar insolvency or resolution authority, which states that the SOFR Administrator has ceased or will cease to provide Term SOFR for a 1-month period permanently or indefinitely, *provided* that, at the time of such statement or publication, there is no successor administrator that will continue to provide Term SOFR for a 1-month period; or (c) a public statement or publication of information by the regulatory supervisor for the SOFR Administrator announcing that Term SOFR for a 1-month period is no longer, or as of a specified future date will no longer be, representative and Agent has provided Borrower with notice of the same, any outstanding affected SOFR Loans will be deemed to have been converted to Credit Extensions that bear interest at a rate based on the Applicable Prime Rate at the end of the Applicable Interest Period.

(iii) In connection with Term SOFR, Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Financing Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Financing Document. Agent will promptly notify Borrower and the Lenders of the effectiveness of any Conforming Changes."

(b) Section 2.6(h) of the Existing Credit Agreement is hereby amended by:

(i) deleting the name of such subsection in its entirety and restating it as follows:

"(h) Taxes; Additional Costs; Increased Costs; Inability to Determine Rates; Illegality."

(ii) adding the following new clause (x) in the appropriate numerical order therein:

"(x) If any Lender shall reasonably determine that the adoption or taking effect of, or any change in, any applicable Law shall (i) impose, modify or deem applicable any reserve, special deposit, compulsory loan, insurance charge or similar requirement against assets of, deposits with or for the account of, or credit extended or participated in by, any Lender, (ii) subject any Lender to any tax of any kind whatsoever with respect to this Agreement, or any SOFR Loan made by it, or change the basis of taxation of payments to such Lender in respect thereof (except for Taxes covered by Section 2.6); or (iii) impose on any Lender any other condition, cost or expense affecting this Agreement or SOFR Loans made by such Lender, and the result of any of the foregoing shall be to increase the cost to such Lender of making or maintaining any Credit Extension the interest on which is determined by reference to Term SOFR (or of maintaining its obligation to make any such Credit Extension), or to reduce the amount of any sum received or receivable by such Lender (whether of principal, interest or any other amount) then, upon request of such Lender, the Borrower will pay to such Lender such additional amount or amounts as will compensate such Lender for such additional costs incurred or reduction suffered."

(iii) renumbering the existing clause (x) as new clause (xi); and

(iv) renumbering the existing clause (xi) as new clause (xii).

(c) Section 2.7 of the Existing Credit Agreement is hereby amended by renumbering such existing Section 2.7 as new Section 2.8.

(d) The Existing Credit Agreement is hereby amended by adding the following as a new Section 2.7:

"2.7 Benchmark Replacement Setting; Conforming Changes.

(a) Upon the occurrence of a Benchmark Transition Event, Agent and Borrowers may (and shall work in good faith to) amend this Agreement to replace the then-current Benchmark with a Benchmark Replacement. Any such amendment will become effective at 5:00 p.m. (New York City time) on the fifth (5th) Business Day after Agent has posted such proposed amendment to all Lenders and Borrower so long as Agent has not received, by such time, written notice of objection thereto from Lenders comprising the Required Lenders. No such replacement will occur prior to the applicable Benchmark Transition Start Date. In connection with the implementation of a Benchmark Replacement, Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Financing Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Financing Document. Agent will promptly notify Borrower and the Lenders of the implementation of any Benchmark Replacement and the effectiveness of any Conforming Changes.

(b) Any determination, decision or election that may be made by Agent or, if applicable, any Lender (or group of Lenders) pursuant to this Section will be conclusive and binding absent manifest error and may be made in its or their sole discretion and without consent from any other party to this Agreement or any other Financing Document, except, in each case, as expressly required pursuant to this Section. Notwithstanding anything to the contrary herein or in any other Financing Document, at any time, (a) if the then-current Benchmark is a term rate (including Term SOFR) and either (i) any tenor for such Benchmark is not displayed on a screen or other information service that publishes such rate from time to time as selected by Agent in its reasonable discretion or (ii) the regulatory supervisor for the administrator of such Benchmark has provided a public statement or publication of information announcing that any tenor for such Benchmark is or will be no longer representative, then Agent may modify the definition of "Applicable Interest Period" (or any similar or analogous definition) for any Benchmark settings at or after such time to remove such unavailable or non- representative tenor, and (b) if a tenor that was removed pursuant to clause (a) above either (i) is subsequently displayed on a screen or information service for a Benchmark or (ii) is not, or is no longer, subject to an announcement that it is or will no longer be representative for a Benchmark, then Agent may modify the definition of "Applicable Interest Period" (or any similar or analogous definition) for all Benchmark settings at or after such time to reinstate such previously removed tenor. Agent will promptly notify Borrower of the removal or reinstatement of any tenor of a Benchmark pursuant to this Section.

(c) Upon Borrower's receipt of notice of the commencement of a Benchmark Unavailability Period, the Applicable Index Rate for any outstanding affected Credit Extensions will be deemed to be the Applicable Prime Rate at the end of the Applicable Interest Period.

(e) New Definitions. Section 15 of the Existing Credit Agreement is hereby amended by adding the following definitions in the appropriate alphabetical order therein:

"**Applicable SOFR Rate**" means, with respect to each day during which interest accrues on a Credit Extension, the rate per annum (expressed as a percentage) equal to (a) Term SOFR for the Applicable Interest Period for such day; or (b) if the then-current Benchmark has been replaced with a Benchmark Replacement pursuant to Section 2.7, such Benchmark Replacement for such day. Notwithstanding the foregoing, the Applicable SOFR Rate shall not at any time be less the Applicable Floor.

"**Available Tenor**" means, as of any date of determination with respect to the then- current Benchmark, (a) if such Benchmark is a term rate, any tenor for such Benchmark (or component thereof) that is or may be used for determining the length of an interest period pursuant to this Agreement or (b) otherwise, any payment period for interest calculated with reference to such Benchmark (or component thereof) that is or may be used for determining any frequency of making payments of interest calculated with reference to such Benchmark pursuant to this Agreement, in each case, as of such date and not including, for the avoidance of doubt, any tenor for such Benchmark that is then- removed from the definition of "Applicable Interest Period" or similar term pursuant to Section 2.7.

"**Benchmark**" means, initially, Term SOFR; *provided* that if a Benchmark Transition Event and its related Benchmark Replacement Date have occurred with respect to Term SOFR or the then-current Benchmark, then "Benchmark" means the applicable Benchmark Replacement to the extent that such Benchmark Replacement has replaced such prior benchmark rate pursuant to Section 2.7.

"**Benchmark Replacement**" means, with respect to any Benchmark Transition Event, the sum of: (a) the alternate benchmark rate that has been selected by Agent giving due consideration to (i) any selection or recommendation of a replacement benchmark rate or the mechanism for determining such a rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a benchmark rate as a replacement to the then-current Benchmark for Dollar-denominated syndicated credit facilities at such time and (b) the related Benchmark Replacement Adjustment; *provided* that, if such Benchmark Replacement as so determined would be less than the Applicable Floor, such Benchmark Replacement will be deemed to be the Applicable Floor for the purposes of this Agreement and the other Financing Documents.

"**Benchmark Replacement Adjustment**" means, with respect to any replacement of the then-current Benchmark with an Unadjusted Benchmark Replacement for any applicable Available Tenor, the spread adjustment, or method for calculating or determining such spread adjustment (which may be a positive or negative value or zero) that has been selected by Agent giving due consideration to any selection or recommendation by the Relevant Governmental Body, or any evolving or then-prevailing market convention at such time, for determining a spread adjustment, or method for calculating or determining such spread adjustment, for such type of replacement for U.S. dollar-denominated syndicated credit facilities at such time.

"**Benchmark Replacement Date**" means the earlier to occur of the following events with respect to the then-current Benchmark: (a) in the case of clause (a) or (b) of the definition of "Benchmark Transition Event", the later of (i) the date of the public statement or publication of information referenced therein and (ii) the date on which the administrator of such Benchmark (or the published component used in the calculation thereof) permanently or indefinitely ceases to provide all Available Tenors of such Benchmark (or such component thereof); or (b) in the case of clause (c) of the definition of "Benchmark Transition Event", the first date on which such Benchmark (or the published component used in the calculation thereof) has been determined and announced by the regulatory supervisor for the administrator of such Benchmark (or such component thereof) to be no longer representative; provided, that such non-representativeness will be determined by reference to the most recent statement or publication referenced in such clause (c) even if any Available Tenor of such Benchmark (or such component thereof) continues to be provided on such date. For the avoidance of doubt, the "Benchmark Replacement Date" will be deemed to have occurred in the case of clause (a) or (b) with respect to any Benchmark upon the occurrence of the applicable event or events set forth therein with respect to all then-current Available Tenors of such Benchmark (or the published component used in the calculation thereof).

"**Benchmark Transition Event**" means the occurrence of one or more of the following events with respect to the then-current Benchmark: (a) a public statement or publication of information by or on behalf of the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that such administrator has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof), permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof); (b) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof), the Federal Reserve Board, the Federal Reserve Bank of New York, an insolvency official or resolution authority with jurisdiction over the administrator for such Benchmark (or such component), or a court or an entity with similar insolvency or resolution authority, which states that the administrator of such Benchmark (or such component) has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof) permanently or indefinitely, *provided* that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof); or (c) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that all Available Tenors of such Benchmark (or such component thereof) are no longer, or as of a specified future date will no longer be, representative. For the avoidance of doubt, a "Benchmark Transition Event" will be deemed to have occurred with respect to any Benchmark if a public statement or publication of information set forth above has occurred with respect to each then-current Available Tenor of such Benchmark (or the published component used in the calculation thereof).

"**Benchmark Transition Start Date**" means, in the case of a Benchmark Transition Event, the earlier of (a) the applicable Benchmark Replacement Date and (b) if such Benchmark Transition Event is a public statement or publication of information of a prospective event, the 90th day prior to the expected date of such event as of such public statement or publication of information (or if the expected date of such prospective event is fewer than 90 days after such statement or publication, the date of such statement or publication).

"**Benchmark Unavailability Period**" means the period (if any) (a) beginning at the time that a Benchmark Replacement Date pursuant to clauses (a) or (b) of that definition has occurred if, at such time, no Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Financing Document in accordance with Section 2.7 and (b) ending at the time that a Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Financing Document in accordance with Section 2.7.

"**Conforming Changes**" means, with respect to either the use or administration of Term SOFR or the use, administration, adoption or implementation of any Benchmark Replacement, any technical, administrative or operational changes (including (a) changes to the definition of "Applicable Interest Period", "Base Rate Index", "Business Day", "Reference Time" or other definitions, (b) the addition of concepts such as "interest period", (c) changes to timing and/or frequency of determining rates, making interest payments, giving borrowing requests, prepayment, conversion or continuation notices, or length of lookback periods, (d) the applicability of Section 2.6(h), and (e) other technical, administrative or operational matters) that Agent decides may be appropriate to reflect the adoption and implementation of Term SOFR or such Benchmark Replacement and to permit the administration thereof by Agent in a manner substantially consistent with market practice (or, if Agent decides that adoption of any portion of such market practice is not administratively feasible or determines that no such market practice exists, in such other manner as Agent decides is reasonably necessary in connection with the administration of this Agreement and the other Financing Documents).

"**Reference Time**" means approximately a time substantially consistent with market practice two (2) SOFR Business Days prior to the first day of each calendar month. If by 5:00 pm (New York City time) on any interest lookback day, Term SOFR in respect of such interest lookback day has not been published on the SOFR Administrator's Website, then Term SOFR for such interest lookback day will be Term SOFR as published in respect of the first preceding SOFR Business Day for which Term SOFR was published on the SOFR Administrator's Website; *provided* that such first preceding SOFR Business Day is not more than three (3) SOFR Business Days prior to such interest lookback day.

"**Relevant Governmental Body**" means the Federal Reserve Board and/or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York or any successor thereto.

"**Second Amendment**" means that certain Amendment No. 2 to Credit and Security Agreement, dated as of September 6, 2022, by and among Borrowers, Agent and the Lenders party thereto.

"**SOFR**" means, with respect to any SOFR Business Day, a rate per annum equal to the secured overnight financing rate for such SOFR Business Day.

"**SOFR Administrator**" means CME Group Benchmark Administration Limited (CBA) (or a successor administrator of Term SOFR selected by Agent in its reasonable discretion).

"**SOFR Administrator's Website**" means the website of the SOFR Administrator, currently at https://www.cmegroup.com/market-data/cme-group-benchmark- administration/term-sofr.html, or any successor source for Term SOFR identified by the SOFR Administrator from time to time.

"**SOFR Business Day**" means any day other than a Saturday or Sunday or a day on which the Securities Industry and Financial Markets Association recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities.

"**SOFR Implementation Date**" means the first day after the end of the Applicable Interest Period during which the Second Amendment shall become effective in accordance with its terms.

"**SOFR Loan**" means a Credit Extension that bears interest at a rate based on Term SOFR.

"**Term SOFR**" means the greater of (a) the forward-looking term rate for a period comparable to such Applicable Interest Period based on SOFR that is published by the SOFR Administrator and is displayed on the SOFR Administrator's Website at approximately the Reference Time for such Applicable Interest Period plus 0.10% and (b) the Applicable Floor. Unless otherwise specified in any amendment to this Agreement entered into in accordance with Section 2.7, in the event that a Benchmark Replacement with respect to Term SOFR is implemented, then all references herein to Term SOFR shall be deemed references to such Benchmark Replacement.

"**Unadjusted Benchmark Replacement**" means the applicable Benchmark Replacement excluding the related Benchmark Replacement Adjustment.

(f) Restated Definitions. The definitions of "Applicable Index Rate", "Applicable Interest Period", "Applicable Interest Rate Determination Date" and "Business Day", set forth in Section 15 of the Existing Credit Agreement are hereby deleted in their entirety and restated to read as follows:

"**Applicable Index Rate**" means, from and after the SOFR Implementation Date, for any Applicable Interest Period, the rate per annum determined by Agent equal to the Applicable SOFR Rate; *provided*, *however*, that in the event that any change in market conditions or any law, regulation, treaty, or directive, or any change therein or in the interpretation of application thereof, shall at any time after the date hereof, in the reasonable opinion of Agent or any Lender, make it unlawful or impractical for Agent or such Lender to fund or maintain Obligations bearing interest based upon the Applicable SOFR Rate, Agent or such Lender shall give notice of such changed circumstances to Agent and Borrower and the Applicable Index Rate for Obligations outstanding or thereafter extended or made by Agent or such Lender shall thereafter be the Applicable Prime Rate until Agent or such Lender determines (as to the portion of the Credit Extensions or Obligations owed to it) that it would no longer be unlawful or impractical to fund or maintain such Obligations or Credit Extensions at the Applicable SOFR Rate. In the event that Agent shall have determined (which determination shall be final and conclusive and binding upon all parties hereto), as of any Applicable Interest Rate Determination Date, that adequate and fair means do not exist for ascertaining the interest rate applicable to any Credit Facility on the basis provided for herein, then Agent may select a comparable replacement index and corresponding margin.

"**Applicable Interest Period**" for each Credit Facility has the meaning specified for that Credit Facility in the Credit Facility Schedule; *provided*, *however*, that, at any time that the Applicable Prime Rate is the Applicable Index Rate, Applicable Interest Period shall mean the period commencing as of the most recent Applicable Interest Rate Determination Date and continuing until the next Applicable Interest Rate Determination Date or such earlier date as the Applicable Prime Rate shall no longer be the Applicable Index Rate; and *provided*, *further*, that, at any time Term SOFR is adjusted as set forth in this Agreement, or re-implemented following invocation of the Applicable Prime Rate as permitted herein, the Applicable Interest Period shall mean the period commencing as of such adjustment or re-implementation and continuing until the next Applicable Interest Rate Determination Date, if any.

"**Applicable Interest Rate Determination Date**" means the second (2nd) Business Day prior to the first (1st) day of the related Applicable Interest Period; *provided*, *however*, that, at any time that the Applicable Prime Rate is the Applicable Index Rate, Applicable Interest Rate Determination Date means the date of any change in the Base Rate Index; and *provided*, *further*, that, at any time Term SOFR is adjusted as set forth in this Agreement, the Applicable Interest Rate Determination Date shall mean the date of such adjustment or the second (2nd) Business Day prior to the first (1st) day of the related Applicable Interest Period, as elected by Agent.

"**Business Day**" means any day except a Saturday, Sunday or other day on which either the New York Stock Exchange is closed, or on which commercial banks in Washington, DC and New York City are authorized by law to close; *provided*, *however*, that when used in the context of a SOFR Loan, the term "Business Day" shall also exclude any day that is not also a SOFR Business Day.

(g) Deleted Definitions. Section 15 of the Existing Credit Agreement is hereby amended by deleting in their entirety the definitions of "Applicable Libor Rate" and "Libor Rate Index" therein.

(h) The Credit Facility Schedule for Credit Facility #1 attached to the Existing Credit Agreement is hereby amended by replacing the definition of "Applicable Floor" therein in its entirety with the following:

(i) **Applicable Floor**: means one half percent (0.50%) per annum.

3. **Conditions to Effectiveness.** This Agreement shall become effective as of the date on which Agent shall have received (including by way of facsimile or other electronic transmission) a duly authorized, executed and delivered counterpart of the signature page to this Agreement from each Borrower, Agent and the Lenders.

4. **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.

5. 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: /s/ Maurice Amsellem
Name: Maurice Amsellem
Title: Authorized Signatory

Signature Page(s)

LENDERS:

ELM 2020-3 TRUST

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

By: /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

ELM 2020-4 TRUST

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

By: /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

Signature Page(s)

BORROWER:

STRATA SKIN SCIENCES. INC.
By: Christopher Lesovitz
Name: Christopher Lesovitz
Title: CFO

Signature Page(s)

Exhibit 23.1

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 Amendment No. 1 to Form S-3 on Form S-1 (File No.'s 333-205797 and 333-226296), Form S-3 (File No.'s 333-262150, 333-261090 and 333-258814) and Form S-8 (File No.'s 333-257867) of our report dated March 31, 2023, with respect to our audits of the consolidated financial statements of STRATA Skin Sciences, Inc. and Subsidiary as of December 31, 2022 and 2021 and for the years ended December 31, 2022 and 2021, which report is included in this Annual Report on Form 10-K of STRATA Skin Sciences, Inc. for the year ended December 31, 2022.

/s/ Marcum LLP

Marcum LLP
Philadelphia, Pennsylvania
March 31, 2023

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Robert Moccia, 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.

STRATA SKIN SCIENCES, INC.

Dated: March 31, 2023

By: /s/ Robert J. Moccia
Robert J. Moccia
President & Chief Executive Officer

Exhibit 31.2

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.

STRATA SKIN SCIENCES, INC.

Dated: March 31, 2023

By: /s/ Christopher Lesovitz
Christopher Lesovitz
Chief Financial Officer

Exhibit 32.1

SECTION 906 CERTIFICATION

CERTIFICATION (1)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Robert Moccia, 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, 2022, 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 31, 2023

/s/ Robert J. Moccia	/s/ Christopher Lesovitz
Robert Moccia President & Chief Executive Officer	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.