UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 0-11635

STRATA SKIN SCIENCES

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, including zip code)
(215) 619-3200
(Issuer's telephone number, including area code)
Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	SSKN	The NASDAQ Stock Market LLC

Securities registered under Section 12(g) of the Exchange Act:
None
(Title of Class)

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

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

Indicate by check mark whether the registrant: (i) 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 (ii) has been subject to such filing requirements for the past 90 days.

Yes [_X _] 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such fi les).

Yes [_X _] 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 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 [X]	Smaller reporting company [X]
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 is a shell company (as defined in Rule 12b-2 of the Act).

Yes [_] No [X]

The number of shares outstanding of our common stock as of June 30, 2019, was 32,903,287 shares. The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $49,145,678, computed by reference to the closing market price $2.49 of the common stock as of June 28, 2019, and 19,737,220 shares held by non-affiliates.

As of March 10, 2020, the number of shares outstanding of our common stock was 33,714,362.

Documents Incorporated by Reference
None

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K, or this Report, are "forward-looking statements." These forward-looking statements include, but are not limited to, statements about the plans, objectives, expectations and intentions of STRATA Skin Sciences, Inc., a Delaware corporation, (referred to in this Report as "we," "us," "our", "registrant" or "the Company") and other statements contained in this Report that are not historical facts. The Private Securities Litigation Reform Act of 1995 (the "Reform Act") provides a safe harbor for forward-looking statements made by or on behalf of the Company. Forward-looking statements in this Report or hereafter included in other publicly available documents filed with the Securities and Exchange Commission, or the Commission, reports to our stockholders and other publicly available statements issued or released by us involve known and unknown risks, uncertainties and other factors which could cause our actual results, performance (financial or operating) or achievements to differ from the future results, performance (financial or operating) or achievements expressed or implied by such forward-looking statements. Such future results are based upon management's best estimates based upon current conditions and the most recent results of operations. When used in this Report, the words "will, " "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" or the negative of such terms and similar expressions identify statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and that are intended to come within the safe harbor protection provided by those sections. Forward-looking statements involve risks, assumptions and uncertainties. There are important factors that could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including our plans, objectives, expectations and intentions and other risks set forth throughout this Annual Report, including under "Item 1, Business," "Item 1A, Risk Factors," and "Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations." These 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;***
- ***the risks related to our identified material weaknesses in our internal controls over financial reporting and our efforts to remediate those controls could adversely affect our ability to report our financial condition and results of operations in timely and accurate manner;***
- ***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.

PART I

Item 1.
Business

Our Company

Overview

We are a medical technology company in Dermatology and Plastic Surgery dedicated to developing, commercializing and marketing innovative products for the treatment of dermatologic conditions. Our products include the XTRAC® excimer laser and VTRAC® lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions.

Corporate Information

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. In March 2017 we sent a notice to the 90 owners of MelaFind devices in the United States informing them that, effective September 30, 2017, we would no longer support the device. We have since discontinued all research and development, sales and support activity related to MelaFind. We continue to maintain the patent portfolio for the related intellectual property, as we believe these assets may have value to a potential developer of similar technology. In 2018, we sold a perpetual license of certain MelaFind assets to a third party for $0.2 million.

May 2018 Equity Financing

On May 29, 2018, we completed the sale and issuance (the “Financing”) of 15,740,741 shares of the Company's common stock to Accelmed Growth Partners L.P. ("Accelmed"), Broadfin Capital, LLC ("Broadfin"), Sabby Management LLC ("Sabby"), Gohan Investments, Ltd. and Dr. Dolev Rafaeli, our President and Chief Executive Officer, for gross proceeds of $17.0 million at a per share price of $1.08. The various stock purchase agreements were entered into on March 30, 2018 (collectively, the “SPAs”).

We incurred approximately $2.3 million of costs related to the Financing during the year ended December 31, 2018, which have been offset against the proceeds in the accompanying financial statements.

In further consideration of entering into their respective stock purchase agreements, Sabby and Broadfin have each entered into separate agreements restricting their abilities to sell their holdings (the “Leak-Out Agreements”). Under the terms of each of the respective Leak-Out Agreements, the stockholder agreed that from the later of (a) the date that the approval by the shareholders of the transactions is deemed effective and (b) the closing of the transactions contemplated pursuant to the SPAs, the stockholder shall not sell dispose or otherwise transfer, directly or indirectly, (including, without limitation, any sales, short sales, swaps or any derivative transactions that would be equivalent to any sales or short positions) any shares of common stock of the Company held by the stockholder or issuable to the stockholder upon conversion of shares of the Company’s Series C Convertible Preferred Stock held by the stockholder, (a)at December 31, 2019, the threshold per share price under the Leak-Out Agreements is $1.4815, subject to adjustment for reverse and forward stock splits and the like, or (b) thereafter, at a price per share reflecting less than the price set forth on the schedule in the Leak-Out Agreements subject to adjustment for reverse and forward stock splits and the like, unless, (1) in the case of either clause (a) or (b), otherwise approved by the Company’s Board of Directors, (2) in the case of clause (b), under a shelf prospectus or such other controlled offering as may be agreed to by the Principal Stockholders (as defined in their respective stock purchase agreements) or (3) in the case of either clause (a) or (b), in a sale pursuant to which any other stockholder(s) of the Company are offered the same terms of sale, including in a merger, consolidation, transfer or conversion involving the Company or any of its subsidiaries. At April 1, 2020 the threshold is $1.6564 and after July 1, 2020 rises to $1.7514 and increases in various increments to $3.24 in April 2023.

In addition, Sabby and Broadfin delivered to us a voting undertaking obligating Sabby and Broadfin to increase their respective "blocker" to 9.99% prior to the record date for the meeting of the shareholders.

The investors in the Financing may receive additional shares, in the event of certain contingencies, as described in the SPAs. 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 are additional contingencies included in the SPAs but the Company has determined they are not probable or estimable and/or contractually obligated at this time.

In connection with the SPAs, we entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Investors to prepare and file with the Commission a registration statement covering the shares of common stock issued in the Financing. The Company filed a registration statement on Form S-3, which became effective on September 24, 2018.

MidCap Credit Facility Extinguishment and Fixed Rate – Term Promissory Note

On May 29, 2018, we entered into a Fourth Amendment to Credit Agreement (the "Amendment"), pursuant to which the Company repaid $3.0 million in principal of the existing $10.6 million credit facility established with MidCap Financial Trust in 2015. The terms of the credit facility were amended to impose less restrictive covenants and lower prepayment fees for the Company and extended the maturity date to May 2022. The Amendment modified the principal payments payable under the Credit Agreement including a period of 18 months where there were no principal payments due. The interest rate on the credit facility was one-month LIBOR plus 7.25%. Principal payments began December 2019. Principal payments beginning December 2019 were $252,000 plus interest per month.

On December 30, 2019, we closed on a $7.3 million loan with a commercial bank pursuant to a one-year Fixed Rate – Term Promissory Note (the "Note"). Our obligations under the Note are secured by an Assignment and Pledge of Time Deposit (the "Agreement"), under which the we have pledged the proceeds of a time deposit account in the amount of the loan to the commercial bank. We fully repaid (including payment of termination and exit fees) our existing long-term debt credit facility with Midcap Financial Trust. The transaction was accounted for as a debt extinguishment and we recorded a loss of $414,000.

XTRAC Systems and VTRAC Systems

The XTRAC 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. It received U.S. Food and Drug Administration ("FDA") clearance in 2000 and has since become a widely recognized treatment for psoriasis, vitiligo and other skin diseases. Psoriasis and vitiligo alone, affect up to 10.5 million people in the U.S. and 190 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 3 to 6 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 is smaller, faster and has a new user interface as compared to previous XTRAC generations. 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. 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. We estimate that there are over 1,000 XTRAC lasers in use in the U.S., of which 820 systems were, as of December 31, 2019, included in the recurring revenue model. The target U.S. audience for XTRAC lasers comprises approximately 3,500 dermatologists who perform disease management. In markets outside the U.S. the XTRAC laser is marketed primarily as a capital sale through a master international distributor to distributors in over twenty-five countries. The VTRAC is marketed exclusively in international markets through the same master international distributor.

In July 2019, we signed a direct distribution agreement with our Korean distributor for a combination of direct capital sales and recurring revenues for the country of South Korea. The term is for twelve months with up to four additional twelve-month terms subject to certain conditions.

Studies have concluded that XTRAC treatment leads to significant improvement in psoriasis plaques and severity scores in as few as 6 to 10 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 $160 per treatment to $250 per treatment. (See "Third Party Reimbursement" below.)

In 2018 the Company filed and 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 simultaneously apply multiple level doses of Narrow Band UVB ("NB-UVB") light at delivery in order to calculate and individualize the maximum non-blistering dose for a particular psoriasis patient. Utilizing the results from these test patches, the physician can design the optimal therapeutic dose treatment for each patient. The optimization should result in a shorter treatment regimen to achieve clearance from the disease.

Psoriasis, the disease

The World Health Organization describes psoriasis as a chronic, noncommunicable, painful, disfiguring and disabling disease for which there is no cure, 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 moderate and severe 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 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 86% 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.

The Nordlys System

In March 2017, we announced that we had become the US distributor for the Nordlys laser, a device representing the latest technology in non-ablative fractionated laser technology in the medical aesthetic field.

In March 2018 we determined we would no longer market the line. In June 2018 the Company terminated the contract and wrote down all inventory and fixed assets related to the product line to the net realizable value and recorded an expense of $280,000 in cost of revenues.

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, RA Medical and pharmaceutical companies producing topical products and systemic 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.

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 six employees. We conduct research and development activities at our facility located in Carlsbad, California. Currently, 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, 2019, 26 issued U.S. patents are in force, and many of these patents have foreign counterparts issued and pending. Of those issued, 10 U.S. patents and one German patent relate to the XTRAC and VTRAC product lines and eighteen U.S. patents. Additionally, the Company maintains 16 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.

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

Government Regulation

Regulations Relating to Products and Manufacturing

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

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 510(k) clearance for our XTRAC Momentum Excimer Laser System platform.

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.

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 Act, or the HITECH Act, which was enacted in February 2009 strengthens and expands the HIPAA Privacy and Security Rules and the restrictions on use and disclosure of patient identifiable health information. HITECH also fundamentally changed a business associate's obligations by imposing a number of Privacy Rule requirements and a majority of Security Rule provisions directly on business associates that were previously only directly applicable to covered entities. HITECH includes, but is not limited to, prohibitions on exchanging patient identifiable health information for remuneration, restrictions on marketing to individuals, and obligations to agree to provide individuals an accounting of virtually all disclosures of their health information. Moreover, HITECH requires covered entities to report any unauthorized use or disclosure of patient identifiable health information, known as a breach, to the affected individuals, the United States Department of Health and Human Services, or HHS, and, depending on the size of any such breach, the media for the affected market. Business associates are similarly required to notify covered entities of a breach. Most of the HITECH provisions became effective in February 2010. HHS had already issued regulations governing breach notification which were effective in September 2009.

HITECH 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 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.

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, 2019, the national rates were as follows:

- 96920 - designated for: the total area less than 250 square centimeters. CMS assigned a 2019 national payment of $166.37 per treatment;
- 96921 - designated for: the total area 250 to 500 square centimeters. CMS assigned a 2019 national payment of $182.25 per treatment; and
- 96922 - designated for: the total area over 500 square centimeters. CMS assigned a 2019 national payment of $248.66 per treatment.

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

Employees

As of December 31, 2019, we had 115 full-time employees, which consisted of two executive officers, two vice presidents, 59 sales and marketing staff, 18 people engaged in manufacturing of lasers, 15 customer-field service personnel, 6 engaged in research and development and 12 finance and administration staff.

Customers

In our international business, we depend for a material portion of our sales in the international arena on several key sub-distributors, and especially on The Lotus Global Group, Inc., doing business as GlobalMed Technologies Co., or GlobalMed, which is our master distributor of the XTRAC and VTRAC products.

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.

We have incurred losses for a number of years and anticipate that we will incur continued losses for the foreseeable 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, 2019, was approximately $3.8 million, and as of December 31, 2019, we had an accumulated deficit of approximately $214.6 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, 2019, combined with the anticipated revenues from the sale of our products, will be sufficient to satisfy our working capital needs, capital asset purchases, outstanding commitments and other liquidity requirements associated with our existing operations through the next 12 months following the filing of this Report.

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.

Due to the delayed filing with the Commission of our Form 10-K for the year ended December 31, 2018, and Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019, we are not currently eligible to use a registration statement on Form S-3 to register the offer and sale of securities which may adversely affect our ability to raise future capital or complete acquisitions.

As a result of the delayed filing with the Commission of our Annual Report on Form 10-K for the year ended December 31, 2018 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019, we will not be eligible to register the offer and sale of our securities using a registration statement on Form S-3 under the Securities Exchange Act of 1934 until November 14, 2020, and there can be no assurance that we will be able to file all such reports in a timely manner in the future. Should we wish to register the offer and sale of additional securities to the public, our transaction costs and the amount of time required to complete the transaction could increase, making it more difficult to execute any such transaction successfully and potentially harming our business, strategic plan and financial condition. Furthermore, if we were to experience delays in making our future periodic filings with the Commission, it could subject us to delisting of our common stock from trading on Nasdaq. The delisting of our common stock could adversely affect the market price of and hinder our stockholders' ability to trade in our common stock, and could also affect our ability to access the capital markets or complete acquisitions. If our shares of common stock were delisted, there could be no assurance of it again being listed for trading on Nasdaq or any other exchange.

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

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

- unforeseen difficulties in integrating operations, technologies, services, accounting and personnel;
- diversion of financial and management resources from existing operations;
- unforeseen difficulties related to entering geographic regions where we do not have prior experience;
- risks relating to obtaining sufficient equity or debt financing; 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 any of our future products or services may fail to gain market acceptance, which could adversely affect our competitive position.

We have generated limited worldwide commercial distribution for our products. In the United States, our XTRAC systems are 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 (such as Botox or topical creams for disease management) that require less time commitment from the dermatologist and yield an attractive return on a dermatologist’s time and investment, we may find that our efforts to increase our base of users are hindered.

We also face a risk that the overall cost of systemic or medications or treatment modalities become less expensive through the development of generics or other means. We may find the pressure to reduce our costs to be competitive which may negatively impact our business.

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.

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 Affordable Care Act, "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 March 10, 2020, 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.

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

In our international business, we depend for a material portion of our sales in the international arena on several key sub-distributors, and especially on GlobalMed, which is our master distributor for our XTRAC and VTRAC products. If we lose GlobalMed or one of these sub-distributors, our sales of phototherapy products are likely to suffer in the short term, which could have a negative effect on our revenues and profitability.

If we fail to execute our recurring revenue strategy outside the United States, we may have difficulty replacing the lost revenue from equipment sales, which would negatively affect our results and operations.

As we begin to transition our international business from capital sales to the recurring revenue model, we will reduce our capital sales in the short term for higher recurring revenue in the long term. If we and our in-country distributors fail to obtain recurring customers timely, it could have a negative impact on our revenues and profitability.

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

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

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

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 or approvals, or equivalents thereof in the U.S. and relevant foreign markets, could hurt our ability to distribute and market our products.

In both our U.S. and foreign markets, we are affected by extensive laws, governmental regulations, administrative determinations, court decisions and similar constraints. Such laws, regulations and other constraints may exist at the federal, state or local levels in the U.S. and at analogous levels of government in foreign jurisdictions. In addition, the formulation, manufacturing, packaging, labeling, distribution, importation, sale and storage of our products are subject to extensive regulation by various federal agencies, including, but not limited to, the FDA and the FTC, State Attorneys General in the U.S., as well as by various other federal, state, local and international regulatory authorities in the countries in which 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 twelve months, or longer, and may or may not require human clinical data. The PMA process is much more costly and lengthy. It may take from eleven months to three years, or even longer, and will likely require significant supporting human clinical data. Delays in obtaining regulatory clearance or approval could adversely affect our revenues and profitability. Although we have obtained 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 will also be 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.

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 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. For example, the Spectranetics Corporation was acquired by Koninklijke Philips N.V in 2017. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to 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.

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 twelve months following the filing of this Report. We plan to fund operations by the recurring revenue generated by the use of the XTRAC lasers 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.

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. One jurisdiction has assessed us an amount of $801,000 for the period from March 2014 through August 2017. We have declined an informal offer to settle at a substantially lower amount and are currently in that jurisdiction’s administrative process of appeal. The second jurisdiction has made an initial preliminary assessment of $724 from June 2015 through March 2018 plus interest of $171 through April 2020. 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, 2019, and 2018, and have estimated our sales and use tax liability to be approximately $3.2 million and $2.7 million, respectively. We believe our sales and use tax accruals have properly recognized that if our arrangements with customers are deemed to be subject to sales tax in a particular state are more likely than not and accordingly, the basis for measurement of the state sales and use tax would be 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 the Company 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.

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.

We face risks related to health epidemics and other outbreaks, which could significantly disrupt our operations.

Our business could be adversely impacted by the effects of a novel strain of coronavirus, which surfaced in Wuhan, China, or other epidemics to the extent that coronavirus or any other epidemic harms the Chinese economy in general. Our Chinese distributor is located in Wuhan, China. While the impact on operations of our distributor is expected to be temporary, the duration of the business disruption, reduced ability to distribute our devices in the country and related financial impact cannot be reasonably estimated at this time and could have a material impact on our financial position and cash flow. Additionally, as the virus spreads to other countries, its impact on the international markets, including South Korea and Japan, could adversely affect our sales and reduce our ability to distribute devices in any and all international markets.

Domestically, as the procedures in which our devices are used are elective in nature; if social distancing, travel restrictions, quarantines or other restrictions become prevalent in the United States this could have a material impact on our recurring revenue model and our financial position and cash flow. The virus has disrupted the supply chain from China and other countries. We depend upon our supply chain, which includes China and other domestic and international markets to provide a steady source of components to manufacture and repair our devices. A shut-down of suppliers within our supply chain would severely disrupt our ability to sell, place and repair our products and this would have a material impact on our financial position and cash flow.

In the event our own employees are impacted through direct or ancillary contact with a person who has the virus, we may need to devise other methods of transacting business in our offices by working from home and or potentially ceasing operations for a period of time.

The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

The extent to which the health emergencies, the spread of infectious disease and pandemics impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Risks Relating to Our Common Stock

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 are additional contingencies included in the SPAs that the Company has determined are not probable or estimable and/or contractually obligated in order to issue shares at this time.

As a result of a financing in June 2015 we incurred significant debt in the form of convertible preferred stock. In order to repay the underlying debt and help make our stock more liquid, we entered into an exchange agreement with holders of the debt and issued them a new class of preferred shares. Any remaining preferred shares, which have not been converted, present dilution risk for our shareholders.

On September 20, 2017, we announced the closing of an exchange transaction pursuant to the Securities Exchange Agreement (the "Exchange Agreement") dated as of June 7, 2017, between us and holders of our June 2015 Debentures and July 2014 Debentures. In closing the exchange transaction, the holders of the Debentures exchanged the Debentures, having an aggregate principal amount of approximately $40.5 million, into 40,482 shares (the "Preferred Shares") of our newly created Series C Convertible Preferred Stock. The Preferred Shares are convertible into a total of approximately 15,049,000 shares of our common stock. Each Preferred Share has a stated value of $1,000 and is convertible into shares of common stock at a conversion price equal to $2.69. As of March 10, 2020, 40,482 Preferred Shares have been converted into 15,049,142 shares of common stock.

In 2019, we have identified material weaknesses in our internal control over financial reporting and such weaknesses have led to a conclusion that our disclosure controls and procedures were not effective for prior periods, including as of December 31, 2018. We have begun our remediation process, however, these material weaknesses have not been remediated. In addition, if we discover additional weaknesses, and we are unable to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting, it could have an adverse effect on our results of operations, our stock price and investor confidence in our Company.

We had previously reported in our Annual Report for the fiscal year ended December 31, 2018 based on our evaluation as of and for the period then ended our disclosure controls and procedures were not effective as of December 31, 2018, due to the material weaknesses described below.

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 Commission 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. The design of any disclosure controls and procedures 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.

Control Environment

In 2019, we identified certain deficiencies in our internal controls relating to the period from 2018 and prior years, which aggregated to a material weakness in the control environment component of the Committee of Sponsoring Organizations of the Treadway Commission in the 2013 *Internal Control - Integrated Framework (the "COSO Framework*). The ineffective control environment resulted in a restatement of the consolidated financial statements of STRATA Skin Sciences, Inc. and Subsidiary as reported in the Company's Annual Report for the year ended December 31, 2018.

Remediation Plans and Activities

We commenced measures to remediate the material weaknesses during the fourth quarter of 2019. Management, with the participation and input of the Audit Committee, was in engaged in remedial activities to address the material weaknesses described above and identified the following root causes:

- We did not have appropriately qualified personnel to meet our control objectives and with an appropriate level of U.S. GAAP knowledge and experience to address the following concerns:
  - Properly review and evaluate the work performed by other Company personnel, outside experts and consultants related to complex accounting matters.
  - Properly select, document and continue evaluation of appropriate accounting policies.
  - Identify and assess risk associated with changes to Company's structure and the impact on internal controls and perform an effective risk assessment.
- We did not have adequate review procedures to assess the adequacy of the work performed by the experts including the applicability of applicable accounting standards.

In order to address the root causes of the material weaknesses described above we have evaluated each of the Company's experts at question and in some cases terminated those relationships. We have planned, documented and executed procedures to test the work performed by experts retained by us and implemented additional management review controls. We have enhanced our documentation as it pertains to the work performed by experts. We have also enhanced our documentation as it pertains to the selection and continued evaluation of accounting policies and implemented additional management review controls. In addition, we committed to a plan on adding an additional experienced headcount with appropriate knowledge and experience in U.S. GAAP.

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We are committed to maintaining a strong internal control environment, and we have performed the root cause analysis and have commenced the remediation process. We believe we are making progress toward achieving the effectiveness of our internal controls and will continue to assess the effectiveness of our internal controls. We will continue to take steps to remediate the above mentioned material weaknesses expeditiously.

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 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.

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, 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 term of the lease runs through January, 2023.

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. We are currently under audit by two taxing jurisdictions, pertaining to sales and/or use tax. One jurisdiction has assessed us an amount of $801,000 for the period from March 2014 through August 2017. We have declined an informal offer to settle at a substantially lower amount and are currently in that jurisdiction’s administrative process of appeal. The second jurisdiction has made an initial preliminary assessment of $724,000 from June 2015 through March 2018 plus interest of $171,000 through April 2020. If it is found we are not exempt from sales tax in these states then potential tax liabilities including interest and penalties would be higher than accrued amounts**.**

Strata Skin Sciences, Inc. v. Ra Medical Systems, Inc., Court of Common Pleas, Montgomery Cty., PA, No. 201821421; *Ra Medical Systems, Inc. v. Strata Skin Sciences, Inc., Uri Geiger, and Accelmed Growth Partners, L.P.*, U.S. District Court for the Southern District of California, No. 19-cv-0920 (AJB/MSB). On August 30, 2018, the Company and its Chairman, Dr. Uri Geiger (collectively, the "plaintiffs"), commenced an action in the Pennsylvania Court of Common Pleas in Montgomery County (the "Pennsylvania Court") against Ra Medical Systems, Inc. ("Ra") seeking a declaratory judgment that (1) the plaintiffs are not liable to Ra for any reason, including but not limited to claims of tortious interference, defamation, libel, or unfair competition and did not otherwise tortiously interfere with Ra's initial public offering, or engage in any other wrongdoing, as a result of statements made in an email issued by Dr. Geiger on May 22, 2018, about which Ra had threatened to initiate litigation; (2) the plaintiffs made no actionable statements to UBS Investment Bank ("UBS") regarding Ra; (3) the Company is not a successor or assign of PhotoMedex, Inc. ("PhotoMedex"); and, therefore, (4) Ra cannot enforce a settlement agreement (the "Ra Settlement Agreement") between PhotoMedex and Ra against the Company. This case arose out of a demand letter issued by Ra relating to Dr. Geiger's May 22, 2018, email to UBS. In that demand letter, Ra asserted that certain statements in the email were false and caused damage to Ra, particularly with respect to Ra's then planned initial public offering. Ra demanded that the statements be affirmatively and publicly retracted and further threatened that Ra would initiate a litigation process in California against the Company pursuant to the Ra Settlement Agreement that Ra entered into with PhotoMedex, a separate and distinct entity, and that Ra asserted was binding on the Company. The Company initiated this action in response to the threat of litigation and the alleged claims. A number of substantive motions filed by the parties remain outstanding, including motions for summary judgment and a motion by the Company to enforce a settlement agreement that the Company contends the parties agreed upon to resolve this matter as well as the California action, discussed immediately below.

Ra commenced an action in the U.S. District Court for the Southern District of California (the "California Court") on May 16, 2019, asserting claims against the Company, its Chairman, Dr. Uri Geiger, and Accelmed Growth Partners, L.P., of which Dr. Geiger is Co-Founder and Managing Partner, for (a) breach of the Ra Settlement Agreement with PhotoMedex, as discussed immediately above; (b) tortious interference with actual and prospective business opportunities; and (c) trade libel. The Company believes that these are the identical claims that form the basis of the Company's action in Pennsylvania. Ra amended its complaint in this California action for the second time, on July 25, 2019. This second amended complaint added a claim against the Company for false advertising under the Lanham Act (15 U.S.C. § 1125(a)), alleging that the Company made false and misleading statements to Ra's customers regarding potential patent infringement claims that the Company may have against Ra. The Company and Dr. Geiger filed motions to dismiss and/or stay the California action on the basis that the action is duplicative of the Pennsylvania action discussed above and any and all related claims should be adjudicated in one forum. Ra has filed a motion to file a supplemental second amended complaint. All motions remain pending.

Although the Company believes it has strong and meritorious defenses, given the uncertainty of litigation, the preliminary stage of these cases, and the legal standards that must be met for, among other things, success on the merits, at this time, the Company cannot provide a reasonable estimate for possible losses that may result from these actions. This estimate may change from time to time, and actual losses could vary. Based upon the filings to date and consultation with counsel, the Company does not believe that these legal proceedings are material to its financial conditions, operations or cash flows.

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 10, 2020, we had 33,714,362 shares of common stock issued and outstanding. This did not include (i) options to purchase 4,908,038 shares of common stock, of which 1,906,275 were vested as of March 10, 2020, (ii) warrants to purchase up to 749,901 shares of common stock, all of which warrants were vested or (iii) vested restricted stock units of 140,082.

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

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, 2019. See Notes 1 and 14 to the consolidated financial statements for additional discussion.

	Number of Securities to be issued Upon Exercise of Outstanding Options	Weighted Average Exercise Price of Outstanding Options	Number of Securities Remaining Available Under Equity Compensation Plans (excluding securities reflected in column (A))
	(A)	(B)	(C)
Equity compensation plans approved by security holders	4,908,038	$ 1.90	432,774
Equity compensation plans not approved by security holders	-	-	-
	4,908,038	$ 1.90	432,774

Recent Issuances of Unregistered Securities

None.

Purchases of Equity Securities

None.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and related notes included elsewhere in this Report. Dollar amounts are reported in thousands, except per share and per treatment data.

Introduction, Outlook and Overview of Business Operations

STRATA Skin Sciences is a medical technology company in Dermatology and Plastic Surgery dedicated to developing, commercializing and marketing innovative products for the treatment of dermatologic conditions. Its products include the XTRAC® excimer laser and VTRAC® lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions.

The XTRAC device is utilized to treat psoriasis, vitiligo and other skin diseases. The XTRAC device received FDA clearance in 2000 and has since become a widely recognized treatment among dermatologists. The system delivers targeted 308um ultraviolet light to affected areas of skin, leading to psoriasis clearing and vitiligo repigmentation, following a series of treatments. As of December 31, 2019, there were 820 XTRAC systems placed in dermatologists' offices in the United States under our dermatology recurring procedure model, up from 746 at the end of December 31, 2018. Under the dermatology recurring procedure 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. There are approximately 7.5 million people in the United States and up to 125 million people worldwide suffering from psoriasis, and 1% to 2% of the world's population suffers from vitiligo. In 2019 over 337,000 XTRAC laser treatments were performed.

Effective February 1, 2017, we entered into an exclusive OEM distribution agreement with Esthetic Education, LLC to be the exclusive marketer and seller of private label versions of the SkinStylus® MicroSystem and associated parts under the name of STRATAPEN. This three-year agreement has minimum annual sales requirements for renewal. The agreement expired in January 2020.

During 2017 we entered into an agreement to license the Nordlys product line from Ellipse A/S. In 2018, following the Financing, we determined we would no longer market the line and the agreement was terminated. We discontinued carrying the Nordlys product line and the distribution agreement with Ellipse A/S was terminated on May 31, 2018.

In July 2019, we signed a direct distribution agreement with our Korean distributor for a combination of direct capital sells and recurring revenues for the country of South Korea. The term is for twelve months with up to four additional twelve-month terms subject to certain conditions.

Key Technology

- *XTRAC® Excimer Laser.* XTRAC originally received FDA clearance in 2000 and has since become a widely recognized treatment among dermatologists for psoriasis and other skin diseases. The XTRAC excimer laser 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 the third quarter of 2018 we announced the launch of our S3, the next generation XTRAC. The S3 is smaller, faster and has a smart user interface.
- In January 2020, we announced the FDA granted clearance of our XTRAC Momentum Excimer Laser platform,
- *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.

Recent Developments

Equity Financing

On May 29, 2018, we completed the sale and issuance (the “Financing”) of 15,740,741 shares of the Company's common stock, subject to customary post-closing adjustments, to Accelmed Growth Partners L.P. ("Accelmed"), Broadfin Capital LLC ("Broadfin"), Sabby Management LLC ("Sabby"), Gohan Investments, Ltd. and Dr. Dolev Rafaeli, our President and Chief Executive Officer, for gross proceeds of $17.0 million at a per share price of $1.08. The various stock purchase agreements were entered into on March 30, 2018 (collectively, the “SPAs”).

We incurred $2.3 million of costs related to the Financing during the year ended December 31, 2018, which have been offset against the proceeds in the accompanying financial statements.

In further consideration of entering into their respective stock purchase agreements, Sabby and Broadfin have each entered into separate agreements restricting their abilities to sell their holdings (the “Leak-Out Agreements”). Under the terms of each of the respective Leak-Out Agreements, the stockholder agreed that from the later of (a) the date that the approval by the shareholders of the transactions is deemed effective and (b) the closing of the transactions contemplated pursuant to the SPA, the stockholder shall not sell dispose or otherwise transfer, directly or indirectly, (including, without limitation, any sales, short sales, swaps or any derivative transactions that would be equivalent to any sales or short positions) any shares of common stock of the Company held by the stockholder on the date hereof or issuable to the stockholder upon conversion of shares of the Company’s Series C Convertible Preferred Stock held by the stockholder on the date hereof, (a) at December 31, 2019, the threshold per share price under the Leak-Out Agreements was $1.48 from April 1 to June 30, 2020, at a price per share of the Company’s common stock less than $1.66 and after July 1, 2020 price per share of $1.75, subject to adjustment for reverse and forward stock splits and the like, or (b) thereafter, at a price per share reflecting less than the price set forth on the schedule in the Leak-Out Agreements subject to adjustment for reverse and forward stock splits and the like, unless, (1) in the case of either clause (a) or (b), otherwise approved by the Company’s Board of Directors, (2) in the case of clause (b), under a shelf prospectus or such other controlled offering as may be agreed to by the Principal Stockholders (as defined in their respective stock purchase agreements) or (3) in the case of either clause (a) or (b), in a sale pursuant to which any other stockholder(s) of the Company are offered the same terms of sale, including in a merger, consolidation, transfer or conversion involving the Company or any of its subsidiaries. At April 1, 2020 the threshold is $1.6564 and after July 1, 2020 rises to $1.7514 and increases in various increments to $3.24 in April 2023.

In addition, Sabby and Broadfin delivered to us a voting undertaking obligating Sabby and Broadfin to increase their respective “blocker” to 9.99% prior to the record date for the meeting of the shareholders.

The investors in the Financing may receive additional shares, in the event of certain contingencies, as described in the SPAs. 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 are additional contingencies included in the SPA’s but the Company has determined they are not probable or estimable and/or contractually obligated at this time.

In connection with the SPAs, we entered into a Registration Rights Agreement (the “Registration Rights Agreement”) with the Investors to prepare and file with the Commission a registration statement covering the shares of common stock issued in the Financing. The Company filed a registration statement on Form S-3, which became effective on September 24, 2018.

MidCap Credit Facility Extinguishment and Fixed Rate-Term Promissory Note

On May 29, 2018, we entered into a Fourth Amendment to Credit Agreement (the "Amendment"), pursuant to which the Company repaid $3.0 million in principal of the existing $10.6 million credit facility established with MidCap Financial Trust in 2015. The terms of the credit facility were amended to impose less restrictive covenants and lower prepayment fees for the Company and extended the maturity date to May 2022. The Amendment modified the principal payments payable under the Credit Agreement including a period of 18 months where there were no principal payments due. The interest rate on the credit facility was one-month LIBOR plus 7.25%. Principal payments beginning December 2019 were $252,000 plus interest per month.

On December 30, 2019, we closed on a $7.3 million loan with a commercial bank pursuant to a one-year Fixed Rate – Term Promissory Note (the "Note"). Our obligations under the Note are secured by an Assignment and Pledge of Time Deposit (the "Agreement"), under which we have pledged, to the commercial bank, the proceeds of a time deposit account in the amount of the loan. We fully repaid (including payment of termination and exit fees) our existing long-term debt credit facility with Midcap Financial Trust. The transaction was accounted for as a debt extinguishment and the Company recorded a loss of $414.

Sales and Marketing

As of December 31, 2019, our sales and marketing personnel consisted of 59 full-time employees, inclusive of a vice president of sales, a 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.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations in this Report are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses and disclosures at the date of the financial statements. On an on-going basis, we evaluate our estimates, including, but not limited to, those related to revenue recognition, accounts receivable, deferred revenues, inventories, useful lives and impairment of property and equipment and of intangibles and goodwill, fair value of equity-based awards, sales and use tax, deferred taxes, financial instruments (derivative instruments and warrants) and accruals for warranty claims. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

Management believes that the following critical accounting policies affect our more significant judgments and estimates in the preparation of our consolidated financial statements.

Revenue Recognition

In the Dermatology Recurring Procedures Segment we have 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.

For the purposes of U.S. GAAP only, these two types of arrangements are treated under the guidance of ASC 842, Leases. While these arrangements are not contractually operating leases, since we sell the physician access codes in order to operate the treatment equipment, these are similar to operating leases for accounting purposes since we provide the customers limited arrangement rights to use the treatment equipment and 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. The terms of the domestic arrangements are generally 36 months with automatic one-year renewals and include a termination clause that can be affected at any time by either party with 30 to 60 day notice. Amounts paid are generally non-refundable. 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 ratably 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, through our Korean distributor, we sell access codes for a fixed amount on a monthly basis to end user customers and the terms are generally 48 months, with termination in the event of the customers' failure to remit payments timely, and includes a potential buy-out at the end of the term of the contract. Pre-paid amounts are recorded in deferred revenue and recognized as revenue over the lease term in the patterns described above. Under both methods, pricing is fixed with the customer.

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

In the Dermatology Procedures Equipment segment we sell our products internationally through distributors and domestically, directly to a physician. For the product sales, we recognize revenues when control of the promised products is transferred to either our distributors or end-user customers, in an amount that reflects the consideration we expect 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, we must have a present right to payment and legal title must have passed to the customer. We ship most of our products FOB shipping point, and as such, we primarily transfer control and record revenue upon shipment. From time to time we will grant certain customers, for example governmental customers, FOB destination terms, and the transfer of control for revenue recognition occurs upon receipt. We have 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.

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 but excludes any equipment accounted for as leases. 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 where the Company has received payments, but has not yet satisfied the related performance obligations. The allocations of the transaction price are based on the price of standalone warranty contracts sold in the ordinary course of business. The advance consideration received from customers for the warranty services is a contract liability that is recognized ratably over the warranty period.

With respect to contract acquisition costs, we applied the practical expedient and expense these costs immediately.

Inventory

We account for inventory at the lower of cost or net realizable value. Cost is determined to be the purchased cost for raw materials and the production cost (labor and indirect manufacturing cost) for work-in-process and finished goods. The cost is determined on the first-in, first-out method. Throughout the laser manufacturing process, the related production costs are recorded within inventory. Work-in-process is immaterial, given the typically short manufacturing cycle, and is therefore included in raw materials. We perform full physical inventory counts for XTRAC and cycle counts on the other inventory to maintain controls and obtain accurate data.

Our XTRAC laser is either (i) sold to distributors or physicians directly or (ii) placed in a physician's office and remains our property. The cost to build a laser, whether for sale or for placement, is accumulated in inventory. When a laser is placed in a physician's office, the cost is transferred from inventory to "lasers in service" within property and equipment. At times, units are shipped to distributors but revenue is not recognized until all of the revenue recognition criteria has been met and, until that time, the unit is included in inventory.

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

Allowance for Doubtful Accounts

Accounts receivable are reduced by an allowance for amounts that may become uncollectible in the future. From time to time, our customers dispute the amounts due to us, and, in other cases, our customers experience financial difficulties and cannot pay on a timely basis. In certain instances, these factors ultimately result in uncollectible accounts. The determination of the appropriate reserve needed for uncollectible accounts involves significant judgment. Such factors include changes in the financial condition of our customers as a result of industry, economic or customer-specific factors. A change in the factors used to evaluate collectability could result in a significant change in the allowance needed. As of December 31, 2019, and 2018, allowance for doubtful accounts was $184 and $141, respectively.

Property and Equipment

As of December 31, 2019, and 2018, we had net property and equipment of $5,369 and $5,301, respectively. The most significant component relates to the XTRAC lasers placed by us in physicians' offices. We own the equipment and charge the physician for access codes for an agreed upon number of treatments. The recoverability of the net carrying value of the lasers is predicated on continuing revenues from the recurring revenue business model. If the physician does not generate sufficient treatments, then we may remove the laser from the physician's office and redeploy it elsewhere. XTRAC lasers placed in service are depreciated on a straight-line basis over the estimated useful life of five-years. For other property and equipment, depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, primarily three to seven years for computer hardware and software, furniture and fixtures, and machinery and equipment. Leasehold improvements are amortized over the lesser of the useful lives or lease terms. Useful lives are determined based upon an estimate of either physical or economic obsolescence, or both.

Goodwill

Our balance sheet includes goodwill which is subject to an annual assessment for impairment under FASB ASC Topic 350, "Goodwill and Other Intangibles" and is not amortizable. Management's judgments regarding the existence of impairment indicators, on an interim or annual basis, are based on various factors, including market conditions and operational performance of our business. As of December 31, 2019, and 2018, we had $8,803 of goodwill accounting for 18.6% and 18.5% of our total assets, respectively. The acquisition of the XTRAC and VTRAC businesses that gave rise to the recorded goodwill closed on June 22, 2015. The determination of the fair value of the reporting units to which the goodwill relates requires management to make estimates and assumptions. We test our goodwill for impairment at least annually. This test is conducted in December of each year in connection with the annual budgeting and forecast process. Also, on a quarterly basis, we evaluate whether events or changes in circumstances have occurred that would negatively impact the realizable value of our intangibles or goodwill.

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. The balance of our goodwill for each of our segments as of December 31, 2019, is as follows: Dermatology Recurring Procedures $7,958 and Dermatology Procedures Equipment $845. We completed our annual goodwill impairment analysis as of December 31, 2019, for our reporting units. Our assessment concluded that there was no impairment of goodwill. Our analysis employed the use of both a market and income approach, with each method given equal 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 its 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.

Intangibles

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, 2019, and 2018, we had $7,955 and $9,765 of intangible assets accounting for approximately 16.8% and 20.6% of our total assets, respectively. 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, and trade names. 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.

Income taxes

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process requires us to estimate our actual current tax exposure and make an assessment of temporary differences resulting from differing treatment of items, for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not more likely than not, we establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statement of operations. Significant management judgment is required in determining any valuation allowance recorded against our deferred tax assets. In the event that we generate taxable income in the jurisdictions in which we operate and in which we have net operating loss carry-forwards, we may be required to adjust our valuation allowance.

ASC Topic 740-10 requires that we recognize in our financial statements the impact of a tax position, if that position will more likely than not be sustained upon examination, based 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 greater than 50%, likely to be recognized upon ultimate settlement with the taxing authority is recorded. We do not have any uncertain tax positions or accrued penalties and interest. If such matters were to arise, we would recognize interest and penalties related to income tax matters in income tax expense.

Stock-based Compensation

We account for stock-based compensation to employees in accordance with the "Share-Based Payment" accounting standard. The standard requires estimating the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the award is recognized as an expense over the requisite service periods in our consolidated statements of operations. For performance-based awards, we recognize the expense only if we deem it probable that the vesting condition will occur. There were no performance awards granted in 2019 or 2018.

The fair value of employee stock options is estimated using a Black-Scholes valuation model. Compensation costs are recognized over the requisite service period. Total stock-based compensation expense was $1,195 and $904 for the years ended December 31, 2019, and 2018, respectively.

Fair Value Measurements

We measure fair value in accordance with Financial Accounting Standards Board Accounting Standards Codification 820, *Fair Value Measurements and Disclosures ("ASC Topic 820")*. ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions there exists a three-tier fair-value hierarchy, which prioritizes the inputs used in measuring fair value.

Results of Operations

The following financial data, in this narrative, are expressed in thousands, except for the earnings per share and per treatment data.

Revenues

The following table presents revenues from our two segments for the periods indicated below:

	For the Year Ended December 31,	
	2019	2018
Dermatology Recurring Procedures	$ 23,713	$ 21,053
Dermatology Procedures Equipment	7,873	8,802
Total Revenues	$ 31,586	$ 29,855

Dermatology Recurring Procedures

Revenues from Dermatology Recurring Procedures for the year ended December 31, 2019 was $23,713 which approximates 337,000 treatments, with prices ranging from $65 to $95 per treatment. Revenues from Dermatology Recurring Procedures for the year ended December 31, 2018 was $21,053 which approximates 300,000 treatments, with prices ranging from $65 to $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 had 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, we use a direct to patient awareness program for XTRAC advertising in the United States, targeting psoriasis and vitiligo patients through a variety of media including television and radio; 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 afflicted with these diseases. With the Financing completed in May 2018, we have and expect to continue to increase spending in the direct to patient programs to drive patients to our partner clinics to increase recurring revenue. The increase in these programs precedes any increase in the recurring revenue as there is a lag between advertising and patients then receiving treatment, which we estimated to be three to nine months.

Revenues from Dermatology Recurring Procedures are recognized over the estimated usage period of the agreed upon number of treatments, as the treatments are being used. As of December 31, 2019, and 2018, we deferred net revenues of $2,286 and $1,927, respectively, which will be recognized as revenue over the remaining usage period.

In the third quarter of 2019, we signed a direct distribution agreement with our Korean distributor for a combination of direct capital sales and recurring revenues for the country of South Korea. This agreement is expected to increase recurring revenues over time, but will have an initial impact of reducing sales of dermatology procedures equipment in the near term as the contract is to apply the same recurring revenue model we have in the United States.

Dermatology Procedures Equipment

For the year ended December 31, 2019, dermatology equipment revenues were $7,873. Internationally, we sold 74 systems for the year ended December 31, 2019, 7 of which were VTRAC systems. Domestically, we sold 6 systems for the year ended December 31, 2019. For the year ended December 31, 2018, dermatology equipment revenues were $8,802. Internationally, we sold 93 systems for the year ended December 31, 2018, 29 of which were VTRAC systems. Domestically, we sold 25 systems for the year ended December 31, 2018.

Additionally, included in the year ended December 31, 2019, was $185 in revenues for 5 Nordlys units (and accessories). For the year ended December 31, 2018, we had $409 in revenues for 6 Nordlys units (and accessories).

Cost of Revenues

The following table illustrates cost of revenues from our two business segments for the periods listed below:

	For the Year Ended December 31	
	2019	2018
Dermatology Recurring Procedures	$ 7,033	$ 7,378
Dermatology Procedures Equipment	4,283	5,357
Total Cost of Revenues	$ 11,316	$ 12,735

Gross Profit Analysis

Gross profit increased to $20,270 for the year ended December 31, 2019, from $17,120 during the same period in 2018. As a percentage of revenues, the gross margin was 64.2% for the year ended December 31, 2019, versus 57.3% during the same period in 2018. The following tables analyze changes in our gross margin, by segment, for the periods presented below:

Company Profit Analysis	For the Year Ended December 31,	
	2019	2018
Revenues	$ 31,586	$ 29,855
Percent increase	5.8%	
Cost of revenues	11,316	12,735
Percent (decrease)	(11.1%)	
Gross profit	$ 20,270	$ 17,120
Gross profit percentage	64.2%	57.3%

Dermatology Recurring Procedures	For the Year Ended December 31,	
	2019	2018
Revenues	$ 23,713	$ 21,053
Percent increase	12.6%	
Cost of revenues	7,033	7,378
Percent (decrease)	(4.7%)	
Gross profit	$ 16,680	$ 13,675
Gross profit percentage	70.3%	65.0%

The primary reasons for the increase in gross profit were the result of lower depreciation expense on lasers placed in the field, higher revenue and utilization. Increases in utilization of lasers placed in the field result in higher margins after fixed costs are covered.

Dermatology Procedures Equipment	For the Year Ended December 31,	
	2019	2018
Revenues	$ 7,873	$ 8,802
Percent (decrease)	(10.6%)	
Cost of revenues	4,283	5, 357
Percent (decrease)	(20.0%)	
Gross profit	$ 3,590	$ 3,445
Gross profit percentage	45.6%	39.1%

The primary reason for the increase in gross profit for the year ended December 31, 2019, compared to the same period in 2018, was primarily the result of product mix, lower overhead allocation and $280 write off of Nordlys property and inventory write off in 2018. There were no comparable write offs in 2019.

Engineering and Product Development

Engineering and product development expenses for the year ended December 31, 2019, decreased to $1,002 from $1,065 for the year ended December 31, 2018. The decrease was due to lower consulting costs associated with the completion of certain engineering projects.

Selling and Marketing Expenses

For the year ended December 31, 2019, selling and marketing expenses increased to $12,003 from $10,624 for the year ended December 31, 2018. The increase was primarily the result of an increase in headcount and associated salary, benefits, commission and travel. In addition, there was an increase to the direct-to-consumer advertising spend.

General and Administrative Expenses

For the year ended December 31, 2019, general and administrative expenses increased to $10,275 from $8,786 for the year ended December 31, 2018. The increase was primarily the result of approximately $2.0 million in accounting and legal costs associated with our restatement of our financial statements as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, higher stock compensation costs and other personnel costs. These costs have been partially offset by lower consulting costs, bank and credit card fees, sales and use tax and office rent.

Interest Expense, net

Interest expense for the year ended December 31, 2019 was $515 compared to $1,142 for the year ended December 31, 2018. The decrease was due to higher interest income on the higher cash equivalent balance in 2019. Interest expense, in connection with our refinancing, is expected to be lower in 2020.

Other (Expense) Income, net

In connection with our pay-off of the MidCap debt in December 2019, we incurred a loss on debt extinguishment of $414.

In 2018 we sold, a perpetual license of certain assets to a third party for a one-time payment of $0.2 million. There were no such transactions in 2019.

Income Taxes

Income tax benefit for the year ended December 31, 2019, was $149 compared to $264 for the year ended December 31, 2018. The benefit was the result of the change in the Tax Cut and Jobs Act (the “Tax Act”) as net operating loss carryforwards generated beginning in 2018 and forward have an indefinite life. The benefit is comprised primarily of the change in deferred tax liability related to goodwill.

Net Loss

The factors described above resulted in net loss of $3,790 during the year ended December 31, 2019, as compared to a net loss of $4,033 during the year ended December 31, 2018.

Non-GAAP adjusted EBITDA

We have determined to supplement our consolidated financial statements, prepared in accordance with U.S. GAAP, presented elsewhere within this Report, with certain non-GAAP measures of financial performance. These non-GAAP measures include non-GAAP adjusted EBITDA.

This non-GAAP disclosure has limitations as an analytical tool, should not be viewed as a substitute for Net Earnings (Loss) determined in accordance with U.S. GAAP, and should not be considered in isolation or as a substitute for analysis of the Company's results as reported under U.S. GAAP, nor is it 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 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 GAAP measure of all non-GAAP measures included in this Report is as follows:

	For the Year Ended December 31,	
	2019	2018
Net loss	$ (3,790)	$ (4,033)
Adjustments:		
Income taxes	(149)	(264)
Depreciation and amortization *	4,821	5,397
Interest expense, net	515	1,142
Non-GAAP EBITDA	1,397	2,242
Stock-based compensation expense	1,195	904
Impairment of lasers placed-in-service	30	321
Loss on extinguishment of debt	414	-
Gain on cancellation of distributor rights agreement	-	(11)
Loss on disposal of property and equipment	-	280
Non-GAAP adjusted EBITDA	$ 3,036	$ 3,736

* Includes depreciation on lasers placed-in-service of $2,660 and $3,484 for the years ended December 31, 2019, and 2018, respectively.

Liquidity and Capital Resources

As of December 31, 2019, we had $6,121 of working capital compared to $14,595 as of December 31, 2018. Cash and cash equivalents and restricted cash were $15,629 as of December 31, 2019, as compared to $16,487, as of December 31, 2018. The decrease in cash is associated with our pay-off of the MidCap debt and additional laser placements, increasing our installed base. The decrease in working capital is primarily the result of the refinance of the debt. At December 31, 2019, the debt is current whereas at December 31, 2018 the debt was primarily classified as long-term.

On June 6, 2017, the Company entered into a Securities Exchange Agreement (the "Agreement") with the holders of its June 2015 Debentures due June 30, 2021, and July 2014 Debentures due July 30, 2021, pursuant to which the holders agreed to exchange all of such outstanding debentures into shares of newly created Series C Convertible Preferred Stock. The stockholders approved the exchange at the stockholders' meeting held on September 14, 2017. The closing of the exchange was effective on September 20, 2017, and $40,465 of principal was exchanged for 40,482 shares of Series C Convertible Preferred Stock.

Other than the limitations on conversions to keep each such holders 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 have no 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 for a total of approximately 15,049,000 shares of common stock.

On March 30, 2018, we entered into a Stock Purchase Agreement (the “Accelmed SPA”) with Accelmed investing $13 million into the Company in exchange for 12,037,037 shares of our common stock. In connection with the proposed Accelmed investment, we entered into two separate stock purchase agreements on March 30, 2018, for approximately $1 million with our current shareholders, Broadfin and Sabby. Upon closing of these transactions, each of Sabby and Broadfin received 925,926 shares of our common stock. Two separate subscription agreements were also executed on March 30, 2018, for $1 million each to purchase 925,926 shares of our common stock.

On December 30, 2019, the Company closed on a $7,275 loan with a commercial bank pursuant to a one-year Fixed Rate – Term Promissory Note (the "Note"). The Company's obligations under the Note are secured by an Assignment and Pledge of Time Deposit (the "Agreement"), under which the Company has pledged the proceeds of a time deposit account in the amount of the loan to the commercial bank. The Company fully repaid (including payment of termination and exit fees) its existing long-term debt credit facility with Midcap Financial Trust. The transaction was accounted for as a debt extinguishment and the Company recorded a loss of $414.

We have experienced recurring operating losses although in both 2019, and 2018 we have generated positive cash flow from operations. Historically, we have been dependent on raising capital from the sale of securities in order to continue to operate and to meet our obligations in the ordinary course of business. We believe that our cash and cash equivalents, combined with the anticipated revenues from the sale of our products and the investment discussed above, will be sufficient to satisfy our working capital needs, capital asset purchases, outstanding commitments and other liquidity requirements associated with our existing operations through the next 12 months following the filing of this Report.

Net cash provided by operating activities was $2,229 for the year ended December 31, 2019, compared to cash provided by operating activities of $2,896 for the year ended December 31, 2018. The cash flows provided by operating activities for the year ended December 31, 2019, were unfavorably impacted by the Company's net loss, and an increase in accounts receivable.

Net cash used in investing activities was $2,791 for the year ended December 31, 2019, compared to cash used in investing activities of $1,785 for the year ended December 31, 2018. The primary reason for the increase in cash used was our investment in lasers placed in service in the dermatology recurring procedures business segment, increasing our installed base.

Net cash used in financing activities was $296 for the year ended December 31, 2019, compared to cash provided by financing activities of $11,307 for the year ended December 31, 2018. In 2019, we paid-off MidCap debt and in 2018 we executed the aforementioned equity financing.

Off-Balance Sheet Arrangements

At December 31, 2019, we had no off-balance sheet arrangements.

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.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

Not applicable.

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

We had previously reported in our Annual Report for the fiscal year ended December 31, 2018 based on our evaluation as of and for the period then ended our disclosure controls and procedures were not effective as of December 31, 2018, due to the material weaknesses described below.

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 Commission 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. The design of any disclosure controls and procedures 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.

Control Environment

In 2019, we identified certain deficiencies in our internal controls, relating to the period from 2018 and prior years, which aggregated to a material weakness in the control environment component of the Committee of Sponsoring Organizations of the Treadway Commission in the 2013 *Internal Control - Integrated Framework (the "COSO Framework*). The ineffective control environment resulted in a restatement of the consolidated financial statements of STRATA Skin Sciences, Inc. and Subsidiary as reported in the Company's Annual Report for the year ended December 31, 2018.

Remediation Plans and Activities

We commenced measures to remediate the material weaknesses during the fourth quarter of 2019. Management, with the participation and input of the Audit Committee, was engaged in remedial activities to address the material weaknesses described above and identified the following root causes:

- We did not have appropriately qualified personnel to meet our control objectives and with an appropriate level of U.S. GAAP knowledge and experience to address the following concerns:

  - Properly review and evaluate the work performed by other Company personnel, outside experts and consultants related to complex accounting matters.
  - Properly select, document and continued evaluation of appropriate accounting policies.
  - Identify and assess risk associated with changes to Company's structure and the impact on internal controls and perform an effective risk assessment.

- We did not have adequate review procedures to assess the adequacy of the work performed by the experts including the applicability of applicable accounting standards.

In order to address the root causes of the material weaknesses described above, we have evaluated each of the expert Companies and in some cases terminated those relationships. We have planned, documented and executed procedures to test the work performed by experts retained by us and implemented additional management review controls. We have enhanced our documentation as it pertains to the work performed by experts. We have also enhanced our documentation as it pertains to the selection and continued evaluation of accounting policies and implemented additional management review controls. In addition, we have committed to a plan on adding an additional experienced headcount with appropriate knowledge and experience in U.S. GAAP.

We are committed to maintaining a strong internal control environment, and we have performed the root cause analysis and have commenced the remediation process. We believe we are making progress toward achieving the effectiveness of our internal controls and we will continue to assess the effectiveness of our internal controls. We will continue to take steps to remediate the above mentioned material weakness expeditiously.

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, 2019. Based on that evaluation, management has concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level described below. Notwithstanding the identified material weaknesses, the Company believes the consolidated financial statements in this Annual Report on Form 10-K fairly represent in all material respects our consolidated financial position and results from operations for the periods presented in accordance with U.S. GAAP.

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 not effective as of December 31, 2019 due to the material weakness discribed above. Notwithstanding the identified material weaknesses, the Company believes the consolidated financial statements in this Annual Report on Form 10-K fairly represent in all material respects our consolidated financial position and results from operations for the periods presented in accordance with U.S. GAAP.

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.

Changes in Internal Control over Financial Reporting

Other than described above in the Item 9A, Controls and Procedures, 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.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our directors currently have terms which will end at our next annual meeting of the stockholders or until their successors are elected and qualify, subject to their prior death, resignation or removal. Officers serve at the discretion of the Board of Directors. There are no family relationships among any of our directors and executive officers. Members of our Board of Directors are encouraged to attend meetings of the Board of Directors and the Annual Meeting of Stockholders. The Board of Directors held ten meetings during 2019.

The following sets forth certain biographical information concerning our current directors and our executive officers as of March 10, 2020.

Name	Position	Age
Dr. Uri Geiger	Chairman of the Board	52
Dr. Dolev Rafaeli	President, Chief Executive Officer and Director	56
David N. Gill	Director	65
Samuel E. Navarro	Director	64
Samuel Rubinstein	Director	80
Nachum Shamir	Director	66
LuAnn Via	Director	66

Dr. Uri Geiger became Chairman of the Board of Directors of the Company effective upon closing of the Financing on May 29, 2018. Dr. Geiger is a co-founder and Managing Partner of Accelmed, a private equity investment firm he co-founded in 2009 focused on medical device companies. Prior to founding Accelmed, Dr. Geiger served as the CEO of Exalenz Bioscience Ltd., a medical technology company from May 2006 until December 2008 and is currently on the board. Prior to that, Dr. Geiger co-founded and was the CEO of GalayOr Networks, a developer of optical components from 2001 until 2003. Dr. Geiger was also the founding partner of Dragon Variation Fund in 2000, one of Israel’s first hedge funds, which was sold to Migdal in 2007. Dr. Geiger was formerly an adjunct professor at Tel Aviv University's Recanati School of Business where he lectured on private equity and venture capital and authored the books "Startup Companies and Venture Capital" and "From Concept to Wall Street." Dr. Geiger served as the Chairman of the Board of Directors of Cogentix Medical from November 2016 until its sale in April 2018 and he is currently on the board of a number of public and private medical device companies. We believe Dr. Geiger's qualifications to serve on our Board of Directors includes his extensive entrepreneurial, management and investment know-how having created and built many successful medical device enterprises.

Dr. Dolev Rafaeli was appointed the Company's Interim Chief Executive Officer effective April 10, 2018, and became the Company's Chief Executive Officer effective upon closing of the Financing on May 29, 2018. Dr. Rafaeli has over 25 years of experience in the healthcare, medical device, consumer and industrial services fields. He served as a Member of the Board of Directors of the company that founded the XTRAC, PhotoMedex (Nasdaq and TASE: PHMD) since 2011 and was its CEO from 2006 to 2017. Under his management at PhotoMedex, he oversaw sales growth from $19 million to over $300 million, driven by increases in brand portfolio, distribution channels and M&A transactions. He was President and CEO of Radiancy, a subsidiary of PhotoMedex, from 2006 to 2017. He also served as General Manager of Orbotech (ORBK-NASDAQ), an automated optical inspection capital equipment manufacturer for the electronics industry in China and Hong Kong. Between 1997 and 2000, Dr. Rafaeli served as CEO of USR Ltd., a global electronics contract manufacturing company providing design, supply chain and manufacturing services to dozens of clients in the communications, consumer and medical device fields. He served as director of operations and managed the Arad manufacturing facility for Motorola in its Land Mobile Product Solutions division, manufacturing and distributing communications, consumer and other infrastructure electronics products. He has extensive experience in mergers and acquisitions, both domestically and internationally, and particularly involving public company acquisitions, including PhotoMedex Inc. (formerly, Nasdaq:PHMD), LCA Vision, Inc. (formerly, Nasdaq: LCAV), FC Global Realty Inc. (OTCBB: FCRE). Dr. Rafaeli graduated with a B.Sc. in industrial engineering and management cum laude and a M.Sc. in operations management from the Technion-Israel Institute of Technology, and holds a Ph.D. in business management from Century University and an MBA (with distinction) from Cornell University.

David N. Gill became a director of the Company effective May 29, 2018, and chairs our Audit Committee. Mr. Gill served as the President and Chief Financial Officer of EndoChoice, Inc., a medical device company focused on gastrointestinal disease from April 2016 through the sale of the company in November 2016 and as Chief Financial Officer from August 2014 to April 2016. Previously, he served as the Chief Financial Officer of INC Research (now known as Syneos), a clinical research organization, from February 2011 to August 2013 after having served as a board member and its Audit Committee chairman from 2007 to 2010. Mr. Gill currently serves on the boards of Melinta Therapeutics, Inc., an infectious disease company, Strongbridge Biopharma, a rare disease company, Evolus, Inc., an aesthetics company, and YmAbs Therapeutics, Inc. an immuno-oncology company. Mr. Gill previously served as a director of Histogenics until July 2019. Earlier in his career, Mr. Gill served in a variety of senior executive leadership roles for several medical device companies including TransEnterix, NxStage Medical, CTI Molecular Imaging, Inc., Novoste Corporation and Dornier Medical. Mr. Gill holds a B.S. degree, cum laude, in Accounting from Wake Forest University and an M.B.A. degree, with honors, from Emory University, and was formerly a certified public accountant. We believe that Mr. Gill's qualifications to serve as a director of the Company include his extensive experience as an executive in the medical device industry and his extensive prior and current service as a director of other public life sciences companies.

Samuel Navarro has served as a member of our Board of Directors since March 2014. Since October 2008, Mr. Navarro has been Managing Partner at Gravitas Healthcare, LLC, which provides strategic advisory services to medical technology companies. From September 2005 to October 2008, Mr. Navarro was Managing Director of Cowen & Co. in New York City and head of their Medical Technology Investment Banking initiatives, leading a team of senior people, and was responsible for building the franchise across all product categories, including M&A/Advisory and financing services and products. From 2001 to 2005, Mr. Navarro was at The Galleon Group running the Galleon Healthcare Fund as a Senior Portfolio Manager. He was responsible for all health care investments across all sectors, including pharmaceutical/biopharmaceutical industries, medical technology and hospital supplies, and all areas of healthcare services. From July 1998 to February 2001, Mr. Navarro was Global Head of Healthcare Investment Banking at ING Barings. Mr. Navarro has also served or serves on the boards of Arstasis, BioSig Technologies, Derma Sciences, MicroTherapeutics, Jomed, PhotoMedex and Pixelux Entertainment. Mr. Navarro received an MBA in Finance from The Wharton School at the University of Pennsylvania, a Master of Science in Engineering from Stanford University and a Bachelor of Science in Engineering from The University of Texas at Austin. We believe Mr. Navarro's qualifications to serve on our Board of Directors include his wealth of knowledge and industry expertise in finance, investment banking, mergers and acquisitions, equity research and investment management experience in the medical device industry.

Shmuel (Milky) Rubinstein became a member of the Board of Directors effective upon closing of the Financing on May 29, 2018. He has served for over 20 years as the Chief Executive Officer and General Manager of Taro Pharmaceuticals Industries, a Nasdaq-listed dermatology company. Under his management, Taro grew to become a multinational company with over 1,000 employees worldwide and turnover of close to $450 million. In 2003 Mr. Rubinstein received the Exceptional Industrialist Award. Prior to joining Taro, he finished an International Marketing Course at the Wharton School of the University of Pennsylvania. Mr. Rubinstein has also served or serves as a board member in Clal Biotechnology Industries, Exalenz, Medison Biotech, Trima Pharma, Kamada Ltd., and as consultant to several companies, including start-ups. Mr. Rubinstein is also a volunteer director at the Medical Research Fund of The Tel Aviv Sourasky Medical Center and The National Authority for Yiddish Culture. We believe Mr. Rubinstein's qualifications to serve on the Board of Directors include his wealth of knowledge and industry expertise in finance, investment banking, mergers and acquisitions, equity research and investment management experience in the dermatology industry.

Nachum (Homi) Shamir became a member of the Board of Directors effective upon closing of the Financing on May 29, 2018. He has been the President and Chief Executive Officer of Luminex Corporation since October 2014. Mr. Shamir previously served, from 2006 to 2014, as President and CEO of Given Imaging, a developer, manufacturer, and marketer of diagnostic products for the visualization and detection of disorders of the gastrointestinal tract. Prior to joining Given Imaging, Mr. Shamir was Corporate Vice President of Eastman Kodak Company and President of Eastman Kodak´s Transaction and Industrial Solutions Group. Additionally, he served over 10 years at Scitex Corporation in positions of increasing responsibility, including President and CEO from 2003 to 2004. Prior to Scitex Corporation, Mr. Shamir held senior management positions at various international companies mainly in the Asia Pacific regions. Mr. Shamir currently serves as a director in Luminex Corp (LMNX) and previously served in Given Imaging (GIVN), Congentix Medical (CGNT) and Invendo Medical GMBH. Mr. Shamir holds a Bachelor of Science from the Hebrew University of Jerusalem and a Masters of Public Administration from Harvard University. We believe Mr. Shamir's qualifications to serve on the Board of Directors include his wealth of knowledge and industry expertise in finance, investment banking, mergers and acquisitions, equity research and investment management experience in the life science industry.

LuAnn Via has served as a member of the Board of Directors since April 2012. From November 2012 through January 2017, Ms. Via was President and CEO of Christopher & Banks Corporation, a specialty retailer of women's clothes; a company operating more than 500 retail stores. Prior to this, Ms. Via served as the President and Chief Executive Officer of Payless ShoeSource, a unit of Collective Brands, Inc., from July 2008 to October 2012 when the company was acquired and taken private. Before joining Payless ShoeSource, from January 2006 Ms. Via served as group divisional President of Lane Bryant and Cacique store chains and as President of Catherines stores, both divisions of Charming Shoppes, Inc. Prior to this, and for more than 20 years, Ms. Via held several leadership positions with a number of top retailers. Ms. Via is a member of Women Corporate Directors and The Committee of 200, a business women's leadership group. We believe Ms. Via's qualifications to serve on the Board of Directors include her experience in retail sales and manufacturing and her extensive experience as a CEO and senior executive of several publicly-listed companies.

With respect to the incumbent members of the Board of Directors, none of the members has, in the past 10 years, been subject to a federal or state judicial or administrative order, judgment, decree or finding, not subsequently reversed, suspended or vacated, relating to any legal proceedings, which include judicial or administrative proceedings resulting from involvement in mail or wire fraud or fraud in connection with any business entity or based on violations of federal or state securities, commodities, banking, or insurance laws and regulations, or any settlement to such actions, and any disciplinary sanction or order imposed by a stock, commodities or derivatives exchange other self-regulatory organization.

Board Leadership Structure

Our Board of Directors administers its risk oversight function as a whole by making risk oversight a matter of collective consideration. While management is responsible for identifying risks, our Board of Directors has charged the Audit Committee of the Board of Directors with evaluating financial and accounting risk, the Compensation/Nominating & Governance Committee of the Board of Directors with evaluating risks associated with employees and compensation. Investor-related risks are usually addressed by the Board as a whole.

Compensation, Nominating and Corporate Governance and Audit Committees

General

Our Board of Directors maintains charters for select committees. In addition, our Board of Directors has adopted a written set of corporate governance guidelines and a code of business conduct and ethics and a code of conduct for our chief executive and senior financial officers that generally formalize practices that we already had in place. We have adopted a Code of Ethics, an Anti-Fraud Program and a policy for compliance with the Foreign Corrupt Practices Act. To view the charters of our Audit and Compensation/Nominating and Corporate Governance Committees, Code of Ethics, corporate governance guidelines, codes of conduct and whistle blower policy, please visit our website at *www.strataskinsciences.com*, under the Corporate Governance section of the Investor Relations page (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). In compliance with Nasdaq rules, the majority of our Board of Directors is
comprised of independent directors. The Board of Directors determined in 2019 that, except for Dr. Geiger, who is our Chairman and Dr. Rafaeli, who is our Chief Executive Officer, all other current members of the Board of Directors are independent under the revised listing standards of Nasdaq.

Compensation/Nominating and Governance Committee.

In 2018 the Board determined that the role of the Nominating and Governance Committee should be assumed by the Compensation Committee, and the committee was renamed the Compensation/Nominating and Governance Committee (the "Compensation/Nominating Committee"). Our Compensation/Nominating Committee discharges the Board of Directors' responsibilities relating to compensation of our Chief Executive Officer and other executive officers, produces an annual report on executive compensation for inclusion in our annual proxy statement and this Report and provides general oversight of compensation structure. Other specific duties and responsibilities of the Compensation/Nominating Committee include:

- reviewing and approving objectives relevant to executive officer compensation;
- evaluating performance and recommending to the Board of Directors the compensation, including any incentive compensation, of our Chief Executive Officer and other executive officers in accordance with such objectives;
- reviewing employment agreements for executive officers;
- recommending to the Board of Directors the compensation for our directors;
- administering our equity compensation plans and other employee benefit plans;
- evaluating human resources and compensation strategies, as needed; and
- evaluating periodically the committee charter.

The Compensation/Nominating and Governance Committee reviews executive compensation from time to time and reports to the Board of Directors, which makes all final decisions with respect to executive compensation. The Compensation/Nominating Committee adheres to several guidelines in carrying out its responsibilities, including performance by the employees, our performance, enhancement of stockholder value, growth of new businesses and new markets and competitive levels of fixed and variable compensation. The report of the Compensation/Nominating and Governance Committee for 2019 is presented below.

In absorbing the duties and responsibilities of the Nominating and Governance Committee, except where the Company is legally required by contract, bylaw or otherwise to provide third parties with the right to nominate directors, the Compensation/Nominating Committee is responsible for recommending to the Board the nominees for election as directors at the annual meeting of stockholders and the persons to be elected by the Board to fill any vacancies on the Board. In making such recommendations, the Compensation/Nominating Committee will consider candidates proposed by stockholders. The Committee will review and evaluate information available to it regarding candidates proposed by stockholders and shall apply the same criteria, and will follow substantially the same process in considering them, as it does in considering other candidates. The Compensation/Nominating Committee is charged with developing and periodically assessing and making recommendations to the Board concerning appropriate corporate governance policies. The Compensation/Nominating Committee also has oversight over the Company's corporate governance guidelines and policies governing the full Board. Other specific duties of the Compensation/Nominating Committee in its role of overseeing corporate governance and succession planning are:

- reviewing and evaluating succession planning for our Chief Executive Officer and other executive officers;
- monitoring the independence of our directors;
- developing and overseeing the corporate governance principles applicable to members of our Board of Directors, officers and employees;
- reviewing and approving director compensation and administering the Non-Employee Director Plan;
- monitoring the continuing education for our directors; and
- evaluating annually the committee charter.

Our Board of Directors has adopted a written charter for the Compensation/Nominating and Governance Committee. The Compensation/Nominating and Governance Committee is currently composed of Nachum Shamir, David N. Gill and Samuel Rubinstein. Our Board of Directors determined that each member of the Compensation/Nominating and Governance Committee as of December 31, 2019, satisfies the independence requirements of Nasdaq. The Compensation/Nominating and Governance Committee held two formal meetings and several informal during 2019.

REPORT OF THE COMPENSATION/NOMINATING AND GOVERANANCE COMMITTEE OF THE BOARD OF DIRECTORS

The Compensation/Nominating and Governance Committee which is composed solely of independent directors of the Board of Directors, assists the Board in fulfilling its responsibilities with regard to compensation matters, and is responsible under its charter for determining the compensation of the Company's executive officers. The Committee has reviewed and discussed the "Executive Compensation" section of this annual report statement with management and recommended to the Board that the section be included in the Annual Report.

The Compensation/Nominating and Governance Committee:
Nachum Shamir, Chair
David N. Gill
Samuel Rubinstein

Audit Committee

Our Board of Directors has established an Audit Committee to assist it in fulfilling its responsibilities for general oversight of the integrity of our consolidated financial statements, compliance with legal and regulatory requirements, the independent auditors' qualifications and independence, the performance of our independent auditors and an internal audit function and risk assessment and risk management. The duties of our Audit Committee include:

- appointing, evaluating and determining the compensation of our independent auditors;
- reviewing and approving the scope of the annual audit, the audit fee and the financial statements;
- reviewing disclosure controls and procedures, internal control over financial reporting, any internal audit function and corporate policies with respect to financial information;
- reviewing other risks that may have a significant impact on our financial statements;
- preparing the Audit Committee report for inclusion in the annual proxy statement;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting and auditing matters;
- approving all related party transactions, as defined by applicable Nasdaq Rules, to which we are a party; and
- evaluating annually the Audit Committee charter.

The Audit Committee works closely with management as well as our independent auditors. The Audit Committee has the authority to obtain advice and assistance from, and receive appropriate funding from us for, outside legal, accounting or other advisors as the Audit Committee deems necessary to carry out its duties.

Our Board of Directors has adopted a written charter for the Audit Committee that meets the applicable standards of the Commission and Nasdaq. The Audit Committee members are David N. Gill, Chair, LuAnn Via, and Samuel Rubinstein. The Audit Committee meets regularly and held fifteen meetings during 2019.

The Board of Directors determined in 2019 that each member of the Audit Committee satisfies the independence and other composition requirements of the Commission and Nasdaq. Our Board has determined that each member of the Audit Committee qualifies as an "audit committee financial expert" under Item 407(d)(5) of Regulation S-K and has the requisite accounting or related financial expertise required by applicable Nasdaq rules.

Stockholder Communications with the Board of Directors

Our Board of Directors has established a process for stockholders to communicate with the Board of Directors or with individual directors. Stockholders who wish to communicate with our Board of Directors or with individual directors should direct written correspondence to Jay Sturm, General Counsel at jsturm@strataskin.com or to the following address (our principal executive offices): Board of Directors, c/o Corporate Secretary, 5 Walnut Grove Drive, Suite 140, Horsham, Pennsylvania 19044. Any such communication must contain:

- a representation that the stockholder is a holder of record of our capital stock;
- the name and address, as they appear on our books, of the stockholder sending such communication; and
- the class and number of shares of our capital stock that are beneficially owned by such stockholder.

Mr. Sturm, as the Corporate Secretary will forward such communications to our Board of Directors or the specified individual director to whom the communication is directed unless such communication is unduly hostile, threatening, illegal or similarly inappropriate, in which case the Corporate Secretary has the authority to discard the communication or to take appropriate legal action regarding such communication

REPORT OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS

The Audit Committee oversees the Company's financial reporting process on behalf of the Board of Directors. Management has the primary responsibility for the financial statements and the reporting process, including the systems of internal control over financial reporting and disclosure controls and procedures. In fulfilling its oversight responsibilities, the Audit Committee reviewed the audited financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2019, with management, including a discussion of the quality, not just the acceptability, of the accounting principles, the reasonableness of significant judgments, and the clarity of disclosures in the financial statements.

The Audit Committee is responsible for reviewing, approving and managing the engagement of the Company's independent registered public accounting firm, including the scope, extent and procedures of the annual audit and compensation to be paid therefore, and all other matters the Audit Committee deems appropriate, including the Company's independent registered public accounting firm's accountability to the Board of Directors and the Audit Committee. The Audit Committee reviewed with the Company's independent registered public accounting firm, which is responsible for expressing an opinion on the conformity of audited financial statements with generally accepted accounting principles, its judgment as to the quality, not just the acceptability, of the Company's accounting principles and such other matters as are required to be discussed with the Audit Committee by the Standards of the Public Company Accounting Oversight Board ("PCAOB"), including PCAOB Auditing Standard No. 1301, *Communications With Audit Committees*, the rules of the Securities and Exchange Commission (SEC) and other applicable regulations, and discussed and reviewed the results of the Company's independent registered public accounting firm's examination of the financial statements. In addition, the Audit Committee discussed with the Company's independent registered public accounting firm the independent registered public accounting firm's independence from management and the Company, including the matters in the written disclosures and the letter regarding its independence by Rule 3526 of the PCAOB regarding the independent registered public accounting firm's communications with the Audit Committee concerning independence. The Audit Committee also considered whether the provision of non-audit services was compatible with maintaining the independent registered public accounting firm's independence.

The Audit Committee discussed with the Company's independent registered public accounting firm the overall scope and plans for its audit, and received from them written disclosures and letter regarding their independence. The Audit Committee meets with the Company's independent registered public accounting firm, with and without management present, to discuss the results of its examinations, its evaluations of the Company's internal control over financial reporting and the overall quality of the Company's financial reporting. The Audit Committee held fifteen meetings during the fiscal year ended December 31, 2019.

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board of Directors (and the Board of Directors has approved) that the audited financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, for filing with the Commission.

AUDIT COMMITTEE:

David N. Gill, chair
LuAnn Via
Samuel Rubinstein

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and beneficial holders of more than 10% of our common stock to file with the Commission initial reports of ownership and reports of changes in ownership of our equity securities. As of March 10, 2020, we believe, based solely on a review of the copies of such reports furnished to us and representations of these persons that all Section 16(a) filing requirements applicable to directors and officers were timely met during the year ended December 31, 2019.

Item 11. Executive Compensation

Executive Officers

During the year ended December 31, 2019, our named executive officers were:

- Dolev Rafaeli, President and Chief Executive Officer (effective April 10, 2018);
- Matthew C. Hill, Chief Financial Officer (effective May 15, 2018);

The biographical information for our current executive officers (other than Dr. Rafaeli, which is included above) are below:

Matthew C. Hill (age 51) assumed the duties of Chief Financial Officer on May 15, 2018. Prior to joining the Company, he was the chief financial officer with operational responsibilities with SS White Dental, a privately held medical device company in the dental space, from 2010. Prior to SS White, Matt served as CFO at Velcera and EP Medsystems, both publicly traded companies, where he was also responsible for public company compliance and participated in capital raising for the companies. Mr. Hill has over 20 years of experience in various capacities in public and private companies, and in public accounting with Grant Thornton LLP. Mr. Hill graduated with a B.S. in accounting from Lehigh University in 1991.

Components of Executive Compensation during 2019

During 2019 our named executive officers received salary, a car allowance, annual bonus, special bonus in recognition of the efforts made by the executives in successfully managing the restatement of the Company's 2017 and 2018 financial statements, successfully managing the Company's efforts to become compliant and current with all of the Company's reporting obligations with the Securities and Exchange Commission and regaining compliance with the Nasdaq Listing Rules, all of which compliance matters have been previously disclosed in the Company's filings, and 401(k) matching contributions.

Dr. Rafaeli, earned an annual bonus based upon the performance of the Company's business during the relevant quarters in which he is employed of each fiscal year. Such bonus during 2019 is achieved, on a quarterly basis, but paid annually, if (a) the Company achieved positive adjusted EBITDA and (b) with such bonus amount determined as a percentage of the average aggregate collected revenue during such quarter from all installed laser machines (pro-rated for machines installed during a quarter) ("Average Revenue per Machine") based upon the following schedule:

Average Revenue per Machine per quarter	Bonus (as a percentage of total company revenue for the relevant quarter)
Up to $8,100	0.50%
$8,101 to $9,600	0.80%
$9,601 to $11,000	1.20%
Above $11,001	1.50%

The Average Revenue per Machine and positive adjusted EBITDA results achieved on a quarterly basis resulted in a payout of $157,930.

Mr. Hill, had a target bonus of $95,000 in 2019, with 75% of such bonus based on achieving certain revenue goals. The balance of the bonus was based on achieving personal goals as agreed with the Chief Executive Officer and approved by the Compensation/Nominating and Governance Committee, which resulted in a total bonus payout of $49,287.

Also, during 2019, each of Dr. Rafaeli and Mr. Hill received award of cash bonuses and stock options in recognition of the efforts made by the executives in successfully managing the restatement of the Company's 2017 and 2018 financial statements, successfully managing the Company's efforts to become compliant and current with all of the Company's reporting obligations with the SEC and regaining compliance with the Nasdaq Listing Rules, all of which compliance matters have been previously disclosed in the Company's filings. The cash awards were as follows: (a) Dr. Rafaeli - $120,000; and (b) Mr. Hill - $100,000.

The stock option grants were granted immediately after the close of business on the second business day after the Company became current in its filings with the SEC, which was November 22, 2019, and were made under the following terms:

	Shares underlying Option Grant	Exercise Price per share	Option Term	Vesting Period
Mr. Hill	150,000	$ 2.46	10 years	1/3 on each anniversary of the date of grant
Dr. Rafaeli	300,000	$ 2.46	10 years	1/3 on each anniversary of the date of grant

SUMMARY COMPENSATION TABLE

The following table includes information for the years ended December 31, 2019, and 2018 concerning compensation for our named executive officers.

Name and Principal Position	Year	Salary ($)	Non-Equity Incentive Plan Compensation ($) (4)	Option Awards ($) (3)	All Other Compensation ($) (5)	Total ($)
Dolev Rafaeli (1), Director, President and Chief Executive Officer	2019	400,000	277,930	466,500	23,200	1,167,630
	2018	289,077	142,853	2,223,490	36,646	2,692,066
Matthew C. Hill (2), Chief Financial Officer	2019	240,000	149,287	233,250	16,000	638,537
	2018	149,169	40,627	225,250	2,800	417,846

(1) Dolev Rafaeli was hired as President and Chief Executive Officer on April 10, 2018.
(2) Matthew C. Hill was hired as Chief Financial Officer on May 15, 2018.
(3) These amounts are equal to the aggregate grant-date fair value with respect to the awards made in the respective year, computed in accordance with FASB ASC Topic 718, before amortization and without giving effect to estimated forfeitures. See the “Stock-based compensation” Note to our consolidated financial statements set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, for the assumptions made in calculating these amounts.
(4) Represents annual bonus amounts paid to the named individuals under the bonus plans in their respective employment agreements, and a special bonus awarded in connection with the resolution of matters related to managing the Company’s efforts to become compliant with all of the Company’s reporting requirements. We discuss these bonus plans in further detail in the section entitled “Components of Executive Compensation during 2019.”
(5) “All Other Compensation” includes a car allowance for Dr. Rafaeli of $12,000 and $8,000 in 2019, and 2018 respectively, a 401(k) match of $11,200 in 2019 and a consulting fee of $28,646 in 2018; and for Mr. Hill includes a car allowance of $4,800 and $2,800 in 2019, and 2018 respectively, and a 401(k) match of $11,200 in 2019.

Overview of Executive Employment Agreements and Payments upon Termination or Change of Control

Employment Agreement with Dr. Dolev Rafaeli

On March 30, 2018, the Company executed an employment agreement with Dr. Rafaeli. The term of the employment agreement commenced on April 10, 2018 until the third anniversary of the closing under the Accelmed-led investment, which term is automatically renewed for one year unless either party provides 60 days' notice prior to the end of the then current term. Dr. Rafaeli's employment with the Company would have terminated if the Accelmed-led investment had terminated prior to closing for any reason.

Dr. Rafaeli's base salary is $400 thousand per year, and he is entitled to bonus compensation based upon the achievement of earnings targets. Dr. Rafaeli was awarded stock options under the Company's 2016 Omnibus Incentive Plan equal to 7.5% of the Company's equity on a fully diluted basis as of immediately following the closing of the Accelmed-led investment. The options were awarded as follows: (i) stock options exercisable for 1,557,628 shares of the Company's common stock were granted on March 30, 2018, at an exercise price of $1.12; and (ii) the balance of the stock options were awarded upon approval by the Company's stockholders of the Accelmed-led investment and the transactions contemplated thereby at the special meeting of stockholders, and the exercise price was equal to the closing trading price of the Company's shares of common stock on Nasdaq on the day of the special meeting. The shares of common stock purchasable upon exercise of the stock options are subject to certain transferability restrictions under the employment agreement and fully vest upon a change of control. The employment agreement also contains provisions for fringe benefits, reimbursement of expenses, nomination for election to the Board, indemnification, vacation, confidentiality, assignment of certain inventions and other intellectual property, covenant not to compete and payments of a lump sum payment equal to base salary over the initial term upon termination, depending upon the type of termination.

Employment Agreement with Matthew C. Hill

On May 15, 2018, Matthew Hill began employment as the Company's Chief Financial Officer. The Company and Mr. Hill executed an employment agreement dated May 15, 2018, in connection with the appointment to the Chief Financial Officer position. Under the terms of the agreement, Mr. Hill receives a base salary of $240,000 and is eligible to receive an annual bonus based on the Company achieving certain goals. The target bonus is set annually. In the event Mr. Hill's employment is terminated, in conjunction with a change of control, he will be entitled to severance equal to 12 months of his base salary, payable subject to execution of a general release in favor of the Company. The agreement also contains non-compete and non-solicitation periods.

Outstanding Equity Awards Value at Fiscal Year-End Table

The following table includes certain information with respect to the value of all unexercised options and unvested shares of restricted stock previously awarded to the executive officers named above at the fiscal year end, December 31, 2019.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END TABLE

	Option Awards					
Name	**Grant Date**	**Number of Securities Underlying Unexercised Options (#) Exercisable (1)**	**Equity Incentive Plan Awards Number of Securities Underlying Unexercised Unvested Options (#)**		**Option Exercise Price ($)**	**Option Expiration Date**
Dolev Rafaeli	11/22/2019	-	300,000	$	2.46	11/22/2029
	5/23/2018	471,083	942,166	$	1.66	5/23/2028
	3/30/2018	908,616	649,012	$	1.12	3/30/2028
Matthew Hill	11/22/2019	-	150,000	$	2.46	11/22/2029
	5/23/2018	83,333	166,667	$	1.66	5/23/2028

(1) Options granted were under the 2016 Omnibus Incentive Plan and options. Dr. Rafaeli’s options granted on March 30, 2018 vest quarterly over three years, all others vest annually over three years. Mr. Hill’s options vest annually over three years.

Director Compensation

During 2019, non-management directors shall receive the following compensation as applicable to each particular director.

1. $70,000 base compensation

2. $80,000 base compensation for the Chairman of the Board

3. $10,000 for the Chairman of the Compensation/Nominating Committee.

4. $20,000 for the Chairman of the Audit Committee

5. $5,000 for membership on each committee (not to be paid to the Chair of the committees)

6. New independent Board members shall receive a one-time grant of $20,000 in the form of restricted stock units.

Base compensation is to be paid no more than 50% in cash; no Director is to receive more than $50,000 in cash; that non-cash payments will be in the form of restricted stock units vesting equally in quarterly tranches over 12 months; and that payment will be made for each quarter in advance.

The table below sets forth our non-employee directors' compensation for the year ended December 31, 2019.

DIRECTOR COMPENSATION TABLE

Name	Fees Earned ($)	Stock Awards ($) (2)	All Other Compensation ($)	Total ($)
Uri Geiger (1)	-	-	-	-
David N. Gill	50,000	45,000	-	95,000
Samuel E. Navarro	35,000	35,000	-	70,000
Samuel Rubinstein	45,000	35,000	-	80,000
Nachum Shamir	40,000	40,000	-	80,000
LuAnn Via	40,000	35,000	-	75,000

(1) Fees of $40,000 paid on behalf of Dr. Geiger were paid to Accelmed.

(2) These amounts are equal to the aggregate grant-date fair value with respect to the awards made in the respective year, computed in accordance with FASB ASC Topic 718, before amortization and without giving effect to estimated forfeitures. See the "Stock-based compensation" Note to our consolidated financial statements set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, for the assumptions made in calculating these amounts.

Limitation on Directors' Liabilities; Indemnification of Officers and Directors

Our Fifth Amended and Restated Certificate of Incorporation, as amended ("Certificate of Incorporation") and bylaws designate the relative duties and responsibilities of our officers, establish procedures for actions by directors and stockholders and other items. Our Certificate of Incorporation and bylaws also contain extensive indemnification provisions, which will permit us to indemnify our officers and directors to the maximum extent provided by Delaware law. Pursuant to our Certificate of Incorporation and under Delaware law, our directors are not liable to us or our stockholders for monetary damages for breach of fiduciary duty, except for (i) any breach of the director's duty of loyalty; (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; breach of duty with respect to dividends and other distributions; or (iv) any transaction from which the director derived an improper personal benefit. We have also entered into indemnity agreements with each director which provides for advancement of expenses and indemnification under certain circumstances.

Directors' and Officers' Liability Insurance

We have obtained directors' and officers' liability insurance, which expires on May 29, 2020. We are required under our indemnification agreements to maintain such insurance for us and members of our Board of Directors.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information set forth in Item 5 of this Report under the heading “Securities Authorized for Issuance Under Equity Compensation Plans” is hereby incorporated by reference.

The following table reflects, as of March 10, 2020, the beneficial common stock ownership of: (a) each of our directors, (b) each executive officer, (c) each person known by us to be a beneficial holder of five percent (5%) or more of our common stock, and (d) all of our executive officers and directors as a group. Unless otherwise provided in the accompanying footnotes, the information used in the table below was obtained from the referenced beneficial owner.

Name and Address of Beneficial Owner [1]	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned [1]
Uri Geiger [9]	12,112,627	35.93%
Dolev Rafaeli. [2]	2,441,241	6.93%
Matthew Hill [3]	93,333	*
David N. Gill [4]	50,974	*
Samuel E. Navarro [5]	200,741	*
Samuel Rubinstein [6]	41,427	*
Nachum Shamir [7]	61,880	*
LuAnn Via [8]	122,031	*
All directors and officers as a group (eight persons)	15,124,254	42.57%
Accelmed Growth Partners LP [9]	12,112,627	35.93%
Broadfin Healthcare Master Fund, Ltd [10]	3,252,913	9.56%
Kent Lake Partners LP[11]	2,701,788	8.01%
Nantahala Capital Management, LLC [12]	2,851,001	8.46%

* Less than 1%.

(1) Beneficial ownership is determined in accordance with the rules of the Commission. Shares of common stock subject to delivery, or subject to options or warrants currently exercisable, or exercisable within 60 days of March 10, 2020, are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Unless otherwise indicated in the footnotes to this table, we believe stockholders named in the table have sole voting and sole investment power with respect to the shares set forth opposite such stockholder's name. Unless otherwise indicated, the listed officers, directors and stockholders can be reached at our principal offices. Percentage of ownership is based on 33,714,362 shares of common stock outstanding as of March 10, 2020.

(2) Includes 931,740 shares of common stock and vested options to purchase 1,509,501 shares of common stock.

(3) Includes 10,000 shares of common stock and vested options to purchase 83,333 shares of common stock.

(4) Includes 15,000 shares and vested restricted stock units of 35,974 shares of common stock.

(5) Includes 20,000 shares, 160,276 vested options to purchase shares of common stock and vested restricted stock units of 20,465 shares of common stock.

(6) Includes 11,300 shares of common stock and vested restricted stock units for 30,127 shares of common stock.

(7) Includes 57,815 shares of common stock and vested restricted stock units for 4,065 shares of common stock.

(8) Includes 40,571 shares, 60,995 vested options to purchase shares of common stock and vested restricted stock units of 20,465 shares of common stock.

(9) The business address of Accelmed Growth Partners L.P. ("Accelmed") is 6 Hachochlim Street, 6th floor, Herzliya Pituach L3 46120 Israel. Accelmed Growth Partners GP ("Accelmed GP"), the General Partner of Accelmed, and Uri Geiger, the Managing Director of Accelmed Growth Partners Management Ltd., which is the management company of Accelmed, each have voting and investment control of the securities held by Accelmed. Dr. Geiger is the Co-Founder and Managing Partner of Accelmed. Each of Accelmed GP and Uri Geiger disclaim beneficial ownership over the securities owned by Accelmed except to the extent of their respective pecuniary interest therein. Accelmed holds 12,112,627 shares of common stock. Dr. Geiger disclaims beneficial ownership of the 12,112,627 shares owned by Accelmed.

(10) The business address of Broadfin Healthcare Master Fund, LTD ("Broadfin") is 20 Genesis Close Ansbacher House, Second Floor, P.O. Box 1344, Grand Cayman KY1-1108, Cayman Islands and the business address of each of Broadfin Capital, LLC and Kevin Kotler is 300 Park Avenue, 25th Floor, New York, New York 10022. Broadfin, Broadfin Capital, LLC and Kevin Kotler have shared voting and investment control of the securities held by Broadfin. Broadfin holds the following securities: (i) 2,952,846 shares of common stock; (ii) warrants to purchase 300,000 shares of common stock at $3.75 per share. The conversion of all preferred stock and the exercise of all warrants referenced in this footnote are subject to a 9.99% blocker. The foregoing information has been derived from a Form 13F filed by Broadfin Capital, LLC on January 17, 2020.

(11) The business address of Kent Lake Partners LP ("Kent Lake") is 591 Redwood Highway, Suite 3260 Mill Valley, California 94941. Kent Lake may be deemed to be the beneficial owner of 2,701,788 shares of common stock held by funds and separately managed accounts under its control, and as the managing member Benjamin Natter may be deemed to be the beneficial owner of those shares. The foregoing has been derived from a Schedule 13G filed by Kent Lake on February 11, 2020.

(12) The business address of Nantahala Capital Management, LLC ("Nantahala ") is 19 Old Kings Highway S, Suite 200, Darien, CT 06820. Nantahala may be deemed to be the beneficial owner of 2,851,001 shares of common stock held by funds and separately managed accounts under its control, and as the managing members of Nantahala, each of Wilmot B. Harkey and Daniel Mack may be deemed to be a beneficial owner of those shares. The foregoing has been derived from a Schedule 13G filed by Nantahala on February 13, 2020.

Item 13. Certain Relationships and Related Transactions, Director Independence

Related Person Transactions

During 2018 the Company had an agreement with the son of a former Board Member for direct to consumer advertising. The Company incurred $13,000 of expense for the year ended December 31, 2018 and no longer uses the service.

On March 30, 2018, the Company entered into the Accelmed Purchase Agreement with Accelmed, pursuant to which Accelmed has agreed to invest $13.0 million to purchase upon closing 12,037,037 shares of the Company's common stock at a price per share of $1.08. The Company may incur additional expenses, or Accelmed may receive additional shares in the event of certain contingencies. The Company is required to reimburse Accelmed for its legal, consulting, due diligence and certain costs related to the proposed transaction, including the reasonable legal fees, disbursements and related charges of Accelmed's counsel in an aggregate amount not to exceed $400,000 (or up to $500,000 in the event of certain contingencies, and subject to no cap in the event the Company's stockholders do not approve the transaction) at the earliest of (i) the closing, or (ii) the termination of Accelmed Purchase Agreement for any reason other than by reason of a breach of the Accelmed Purchase Agreement by Accelmed.

Upon closing under the Accelmed Purchase Agreement, Accelmed was the largest shareholder of the Company.

The Accelmed Purchase Agreement also requires that the Company indemnify Accelmed for certain items as defined in the Accelmed Purchase Agreement, which may result in the issuance of additional shares of the Company's common stock to the Investors in the event the Company incurs additional cash obligations above the thresholds contained in the Accelmed purchase Agreement, including excess amounts from sales taxes, broker fees, insurance coverage and legal fees (the "Retained Risk Provisions"). Pursuant to the Retained Risk provisions, Accelmed received an additional 75,590 shares.

In connection with the Accelmed investment, the Company entered into two separate stock purchase agreements on March 30, 2018, each for $1.0 million with two then current stockholders, Broadfin and Sabby. Upon closing of these transactions with the closing under the Accelmed Purchase Agreement, each of Sabby and Broadfin received 925,926 shares of the Company's common stock at a price per share of $1.08. Under the Retained Risk Provisions of the agreements, Broadfin received an additional 41,759 shares and Sabby received an additional 24,027 shares.

The Company also entered into two separate subscription agreements in connection with the Accelmed investment: (i) a subscription agreement with Gohan Investments, Ltd. for $1.0 million to purchase 925,926 shares of our common stock at $1.08 per share; and (ii) a subscription agreement with Dr. Dolev Rafaeli for $1.0 million to purchase 925,926 shares of our common stock at $1.08 per share upon closing under the Accelmed Purchase Agreement.

Pursuant to the Retained Risk Provisions, each of Gohan Investments and Dr. Rafaeli received an additional 5,814 shares.

In connection with the certain litigation with RA Medical, the Company has agreed to indemnify Uri Geiger and Accelmed Growth Partners, L.P. for their out of pocket costs. During the year ended December 31, 2019, the Company has reimbursed Accelmed Growth Partners, L.P. approximately $25.

Director Independence

As required under the Nasdaq, listing standards, a majority of the members of a listed Company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our board of directors consults with internal counsel to ensure that the board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent Nasdaq listing standards, as in effect from time to time. Consistent with these considerations, after review of all relevant transactions or relationships between each director, or any of his or her family members, and our company, our senior management and our independent registered public accounting firm, the board of directors has affirmatively determined that The Board of Directors determined in 2019 that, except for Dr. Geiger, who is our Chairman and Dr. Rafaeli, who is our Chief Executive Officer, all other current members of the Board of Directors are independent under the revised listing standards of Nasdaq.

Review, Approval or Ratification of Transactions with Related Persons

In accordance with its charter, the Audit Committee is responsible for reviewing all "related party transactions" (defined as such transactions required to be disclosed pursuant to Item 404 of Regulation S-K) on an on-going basis. All such related party transactions must be approved by the Audit Committee.

Item 14. Principal Accounting Fees and Services

The following table shows the fees paid or accrued by us for the audit and other services provided by Marcum LLP for 2019, and 2018:

	2019	2018
Audit Fees [1]	$ 266,500	$ 579,000
Audit-Related Fees [2]	-	125,000
Tax Fees [3]	-	-
All Other Fees [4]	-	-
Total	$ 266,500	$ 704,000

(1) Consists of fees billed for the audit of our annual financial statements, review of financial statements included in our Quarterly Reports on Form 10-Q and services that are normally provided by the auditors in connection with statutory and regulatory filings or engagements. These services were billed in 2019 following Marcum's engagement in 2019.

(2) Consists of assurance and related services that are reasonably related to the performance of the audit and reviews of our financial statements and are not included in "audit fees" in this table.

(3) Consists of all tax related services.

(4) There were no other fees billed by Marcum LLP for the years ended December 31, 2019, and 2018.

Engagement of the Independent Auditor

The Audit Committee is responsible for approving every engagement of Marcum LLP to perform audit or non-audit services for us before Marcum LLP is engaged to provide those services. Under applicable Commission rules, the Audit Committee is required to pre-approve the audit and non-audit services performed by the independent auditors in order to ensure that they do not impair the auditors' independence. The Commission's rules specify the types of non-audit services that an independent auditor may not provide to its audit client and establish the Audit Committee's responsibility for administration of the engagement of the independent auditors.

Consistent with the Commission's rules, the Audit Committee Charter requires that the Audit Committee review and pre-approve all audit services and permitted non-audit services provided by the independent auditors to us or any of our subsidiaries. The Audit Committee may delegate pre-approval authority to a member of the Audit Committee and if it does, the decisions of that member must be presented to the full Audit Committee at its next scheduled meeting.

The Audit Committee's pre-approval policy provides as follows:

- First, once a year when the base audit engagement is reviewed and approved, management will identify all other services (including fee ranges) for which management knows it will engage Marcum LLP for the next 12 months. Those services typically include quarterly reviews, specified tax matters, certifications to the lenders as required by financing documents, consultation on new accounting and disclosure standards and, in future years, reporting on management's internal controls assessment.

- Second, if any new "unlisted" proposed engagement arises during the year, the engagement will require approval of the Audit Committee.

All fees to our independent accounting firms were approved by the Audit Committee.

Auditor Selection for Fiscal 2020

The Audit Committee has selected Marcum LLP to serve as our independent auditors for the year ending December 31, 2020.

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, 2019, and 2018, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years ended December 31, 2019, and 2018.

(a)(2) Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, or the information is otherwise set forth in the consolidated financial statements or notes thereto.

(a)(3) Exhibits

The exhibits listed under subsections (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. 333-167113), as filed on May 26, 2010).
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).
3.3	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 contained in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 filed on August 7, 2013).
3.4	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 contained in our Current Report on Form 8-K, filed on July 10, 2014).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 contained in our Current Report on Form 8-K, filed on February 3, 2014).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 contained in our Current Report on Form 8-K, filed on July 23, 2014).
3.7	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 contained in our Current Report on Form 8-K, as filed on September 30, 2015).
3.8	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1 contained in our Current Report on Form 8-K, as filed on January 8, 2016).
3.9	Certificate of Designations of Series C Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 contained in our Current Report on Form 8-K, as filed on September 25, 2017).
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	Warrant dated May 7, 2009 issued by Electro-Optical Sciences, Inc. to Kingsbridge Capital Limited (Incorporated by reference to our Current Report on Form 8-K filed on May 8, 2009).
4.3	Warrant Agreement, dated as of April 26, 2013, by and between MELA Sciences, Inc. and Hercules Technology Growth Capital, Inc. (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 filed on April 30, 2013).
4.4	Form of Series A Warrant (Incorporated by reference to our Current Report on Form 8-K filed on October 30, 2013).

4.5	Form of Series B Prefunded Warrant (Incorporated by reference to our Current Report on Form 8-K filed on October 30, 2013).
4.6	Form of Common Stock Purchase Warrant (Incorporated by reference to our Current Report on Form 8-K filed on February 3, 2014).
4.7	Form of Series [A/B] Common Stock Purchase Warrant (Incorporated by reference to our Current Report on Form 8-K filed on July 23, 2014).
4.8	Form of 4% Senior Secured Convertible Debenture Due July 24, 2019 (Incorporated by reference to our Current Report on Form 8-K filed on July 23, 2014).
4.9	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 contained in our Form 8-K current report, filed on June 23, 2015).
4.10	Form of 9.0% Senior Secured Notes (Incorporated by reference to Exhibit 4.2 contained in our Form 8-K current report, filed on June 23, 2015).
4.11	Form of 2.25% Series A Senior Secured Convertible Debenture (Incorporated by reference to Exhibit 4.3 contained in our Form 10-Q quarterly report for the quarter ended June 30, 2015 filed on August 14, 2015).
4.12	Form of 2.25% Series B Senior Unsecured Convertible Debenture (Incorporated by reference to Exhibit 4.4 contained in our Form 10-Q quarterly report for the quarter ended June 30, 2015 filed on August 14, 2015).
4.13	Form of Warrant Amendment Agreement (Incorporated by reference to Exhibit 4.1 contained in our Current Report on Form 8-K, filed on January 22, 2016).
4.14*	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)
4.15*	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)
10.1*	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 Securities Purchase Agreement dated as of June 22, 2015 by and among the company and the purchasers (Incorporated by reference to our Form 8-K current report, as filed on June 23, 2015).
10.4	Registration Rights Agreement dated as of June 22, 2015 by and among the Company and the purchasers (Incorporated by reference to our Form 8-K current report, as filed on June 23, 2015).
10.5	Security Agreement dated as of June 22, 2015 by and among the Company and parties thereto (Incorporated by reference to our Form 8-K current report, as filed on June 23, 2015).
10.6	Licensing Agreement between the Registrant and KaVo Dental GmbH, dated as of December 5, 2006. (Incorporated by reference to our Current Report on Form 8-K filed on December 11, 2006).
10.7	Securities Purchase Agreement dated as of July 21, 2014 between MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 14, 2014).
10.8	Registration Rights Agreement dated as of July 21, 2014 between MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 14, 2014).
10.9	Security Agreement dated as of July 21, 2014 among MELA Sciences, Inc., all of the Subsidiaries of the Registrant and the holders of the Registrant's 4% Senior Secured Convertible Debentures (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 14, 2014).
10.10	Agreement of Lease, dated as of July 14, 2009, by and between Stanford Bridge LLC and Electro-Optical Sciences, Inc. (Incorporated by reference to our Current Report on Form 8-K filed on July 14, 2009).
10.11	Supply Agreement with Arrow Electronics, Inc., dated April 8, 2011 (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011 filed on August 5, 2011).
10.12	Production Agreement, dated as of January 6, 2012, by and between MELA Sciences, Inc. and Askion GmbH (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 filed on May 3, 2012).

10.13	Service Agreement, dated March 21, 2012, by and between MELA Sciences, Inc. and QUINTILES Commercial Germany GmbH (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 filed on May 3, 2012).
10.14	Asset Purchase Agreement dated as of June 22, 2015 by and among the Company and parties identified on the signature pages thereto. (Incorporated by reference to our Form 8-K current report, as filed on June 23, 2015.)
10.15	Amended and Restated Security Agreement dated as of August 3, 2015 by and among the Company and the parties thereto. (Included in Exhibit 10.8 filed incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed on August 14, 2015).
10.16	MELA Sciences, Inc. Amended and Restated 2013 Stock Incentive Plan (Incorporated by reference to the Registrant's Proxy Statement on Schedule 14A filed on August 24, 2015).
10.17	Loan and Security Agreement, dated as of March 15, 2013, by and between MELA Sciences, Inc. and Hercules Technology Growth Capital, Inc. (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 filed on April 30, 2013).
10.18	Amended and Restated Security Agreement dated as of August 3, 2015 by and among the Company and the parties thereto. (Included in Exhibit 10.8 filed incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed on August 14, 2015.).
10.19	Form of Securities Purchase Agreement, dated as of October 29, 2013, by and among MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to our Current Report on Form 8-K filed on October 30, 2013).
10.20	Omnibus Amendment to 2014 Transaction Documents dated as of August 3, 2015 by and among the Company and the purchases identified therein. (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed on August 14, 2015.).
10.21	Form of Securities Purchase Agreement, dated as of January 31, 2014, by and among MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to our Current Report on Form 8-K filed on February 3, 2014).
10.22	Form of Registration Rights Agreement, dated as of February 5, 2014, by and among MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to our Current Report on Form 8-K filed on February 3, 2014).
10.23	Intentionally omitted.
10.24	Warrant Amendment Agreement dated as of June 22, 2015 (effective September 30, 2015) by and among the Company and parties identified on the signature pages thereto (Incorporated by reference to Exhibit 10.5 contained in our Form 8-K current report filed on June 23, 2015).
10.25*	Consulting Agreement, dated as of November 4, 2015 between the Company and Jeffrey F. O'Donnell, Sr. (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 16, 2015).
10.26*	Consulting Agreement, dated as of November 4, 2015 between the Company and Samuel E. Navarro (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 16, 2015).
10.27*	Transition Agreement and Release dated as of November 9, 2015 between the Company and Robert W. Cook (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 16, 2015).
10.28*	Employment Agreement dated as of November 9, 2015 between the Company and Christina L. Allgeier (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 16, 2015).
10.31	Amended and Restated Employment Agreement, dated as of December 15, 2015 by and between the Company and Michael R. Stewart (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on December 15, 2015).
10.32	Restricted Stock Award Agreement, dated as of December 15, 2015 by and between the Company and Michael R. Stewart (Incorporated by reference to Exhibit 10.2 contained in our Current Report on Form 8-K, as filed on December 15, 2015).
10.33	Warrant to purchase shares of the Company's common stock issued December 30, 2015 to Lender under the Credit Agreement. (Incorporated by reference to Exhibit 10.3 contained in our Current Report on Form 8-K, as filed on January 5, 2016).

10.34	Subordination Agreements dated as of December 30, 2015 among subordinated lenders, the Company and Midcap. (Incorporated by reference to Exhibit 10.4 contained in our Current Report on Form 8-K, as filed on January 5, 2016).
10.35	Omnibus Amendment to 2014 Transaction Documents and 2015 Transaction Documents dated as of December 30, 2015 among the Company and the holders of outstanding debentures under the 2014 and 2015 security purchase agreements. (Incorporated by reference to Exhibit 10.5 contained in our Current Report on Form 8-K, as filed on January 5, 2016).
10.36	Warrant to purchase shares of the Company's common stock issued January 29, 2016 to Lenders under the Credit Agreement. (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on February 1, 2016).
10.37	Omnibus Amendment to 2015 Transaction Documents dated as of August 3, 2015 by and among the Company and the purchases identified therein. (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed on August 14, 2015.).
10.38	Amended and Restated Intellectual Property Security Agreement dated as of August 3, 2015 by and among the Company and the parties thereto. (Included in Exhibit 10.8 filed incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed on August 14, 2015.).
10.39	Intercreditor Agreement dated as of August 3, 2015 by and among the Company and the parties thereto. (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, filed on August 14, 2015.).
10.40*	Extension Agreement dated as of July 20, 2016 between Strata Skin Sciences, Inc. and Jeffrey F. O'Donnell, Sr. (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on July 22, 2016).
10.41*	Extension Agreement dated as of July 20, 2016 between Strata Skin Sciences, Inc. and Samuel E. Navarro. (Incorporated by reference to Exhibit 10.2 contained in our Current Report on Form 8-K, as filed on July 22, 2016).
10.42	First Amendment to Credit and Security Agreement dated as of August 9, 2016 among MidCap Financial Trust, as administrative agent, the Lenders as listed on the signature pages thereto and the Company. (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on August 12, 2016).
10.43	Amended and Restated Fee Letter Agreement dated as of August 9, 2016, by and between Midcap Financial Trust as Agent and the Company. (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on August 12, 2016).
10.44*	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).
10.45*	Employment Agreement between the Company and Frank J. McCaney dated as of October 31, 2016. . (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 14, 2016).
10.46*	Stock Option Agreement between the Company and Frank J. McCaney dated as of October 31, 2016. (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 14, 2016).
10.50*	Severance and Release Agreement between the Company and Michael R. Stewart dated as of October 31, 2016. (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2015 filed on November 14, 2016).
10.51	Second Amendment to Credit and Security Agreement dated as of November 10, 2017, among MidCap Financial Trust, as administrative agent, the Lenders as listed on the signature pages thereto and the Company. Second Amendment to Credit and Security Agreement dated as of November 10, 2017, among MidCap Company (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2017, filed on November 14, 2017).
10.52	Amended and Restated Fee Letter Agreement dated as of November 10, 2017, by and between MidCap Financial Trust as Agent and the Company. (Incorporated by reference to our Form 10-Q quarterly report for the quarter ended September 30, 2017 filed on November 14, 2017).
10.53	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)

10.54	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).
10.55	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).
10.56	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).
10.57	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).
10.58	Form of Voting Undertaking (Incorporated by reference to Exhibit 10.6 contained in our Current Report on Form 8-K, as filed on April 2, 2018).
10.59	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).
10.60*	Employment Agreement dated March 30, 2018, between the Company and Dr. Dolev Rafaeli (Incorporated by reference to Exhibit 10.8 contained in our Current Report on Form 8-K, as filed on April 2, 2018).
10.61	Third Amendment to Credit and Security Agreement, dated as of March 26, 2018, among the Company, MidCap Financial Trust and the lenders signatory thereto (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on April 2, 2018).
10.62*	Employment Agreement effective as of May 15, 2018, between the Company and Matthew C. Hill (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on May 15, 2018).
10.63*	Amended and Restated Strata Skin Sciences, Inc. 2016 Omnibus Incentive Plan (Incorporated by reference to Appendix B to our Definitive Proxy Statement on Schedule 14A, as filed on April 27, 2018).
10.64	Fourth Amendment to Credit and Security Agreement, dated as of May 29, 2018, among the Company, MidCap Financial Trust and the lenders signatory thereto (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on May 29, 2018).
10.65	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).
10.66	Fixed Rate – Term Promissory Note with Israel Discount Bank of New York as of December 31, 2019 (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on January 6, 2019).
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
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema
101.CAL	XBRL Taxonomy Calculation Linkbase
101.DEF	XBRL Taxonomy Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Presentation Linkbase

* 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, as amended, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

STRATA SKIN SCIENCES, INC.

March 17, 2020

By: /s/ Dolev Rafaeli
Dolev Rafaeli
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Capacity in Which Signed	Date
/s/ Dolev Rafaeli Dolev Rafaeli	President, Chief Executive Officer (Principal Executive Officer), and Director	March 17, 2020
/s/ Matthew Hill Matthew Hill	Chief Financial Officer (Principal Financial and Accounting Officer)	March 17, 2020
/s/ Uri Geiger Uri Geiger	Director, Chairman of the Board	March 17, 2020
/s/ David Gill David Gill	Director	March 17, 2020
/s/ Samuel Navarro Samuel Navarro	Director	March 17, 2020
/s/ Shmuel Rubinstein Shmuel Rubinstein	Director	March 17, 2020
/s/ Nachum Shamir Nachum Shamir	Director	March 17, 2020
/s/ LuAnn Via LuAnn Via	Director	March 17, 2020

STRATA SKIN SCIENCES, INC. AND SUBSIDIARY

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, 2019 and 2018, 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, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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.

/s/ Marcum LLP

Marcum LLP

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

Philadelphia, Pennsylvania
March 17, 2020

STRATA SKIN SCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,129	$ 16,487
Restricted cash	7,500	-
Accounts receivable, net	4,386	3,393
Inventories	3,027	2,794
Prepaid expenses and other current assets	513	536
Total current assets	23,555	23,210
Property and equipment, net	5,369	5,301
Operating lease right-of-use assets	1,314	-
Intangible assets, net	7,955	9,765
Goodwill	8,803	8,803
Other assets	347	428
Total assets	$ 47,343	$ 47,507
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Note payable	$ 7,275	$ -
Current portion of long-term debt	-	252
Accounts payable	1,880	1,764
Other accrued liabilities	5,134	4,500
Deferred revenues	2,832	2,099
Current portion of operating lease liabilities	313	-
Total current liabilities	17,434	8,615
Long-term liabilities:		
Long-term debt, net	-	7,145
Long-term operating lease liabilities; net	1,078	-
Deferred tax liability	-	111
Other liabilities	178	388
Total liabilities	18,690	16,259
Commitments and contingencies (see Note 11)		
Stockholders' equity:		
Series C Convertible Preferred Stock, $.10 par value, 10,000,000 shares authorized; 2,103 and 9,968 shares issued and outstanding as of December 31, 2019 and 2018, respectively	1	1
Common Stock, $.001 par value, 150,000,000 shares authorized; 32,932,273 and 29,943,086 shares issued and outstanding as of December 31, 2019 and 2018, respectively	33	30
Additional paid-in capital	243,180	241,988
Accumulated deficit	(214,561)	(210,771)
Total stockholders' equity	28,653	31,248
Total liabilities and stockholders’ equity	$ 47,343	$ 47,507

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 amounts)

	For the Year Ended December 31,	
	2019	2018
Revenues, net	$ 31,586	$ 29,855
Cost of revenues	11,316	12,735
Gross profit	20,270	17,120
Operating expenses:		
Engineering and product development	1,002	1,065
Selling and marketing	12,003	10,624
General and administrative	10,275	8,786
	23,280	20,475
Loss from operations	(3,010)	(3,355)
Other (expense) income, net:		
Interest expense, net	(515)	(1,142)
Loss on extinguishment of debt	(414)	-
Other income, net	-	200
	(929)	(942)
Loss before income taxes	(3,939)	(4,297)
Income tax benefit	149	264
Net loss	$ (3,790)	$ (4,033)
Loss attributable to common shares	$ (3,597)	$ (2,909)
Loss attributable to Preferred Series C shares	$ (193)	$ (1,124)
Loss per common share:		
Basic	$ (0.11)	$ (0.15)
Diluted	$ (0.11)	$ (0.15)
Shares used in computing loss per common share:		
Basic	31,978,665	19,589,031
Diluted	31,978,665	19,589,031
Loss per Preferred Series C share - basic and diluted	$ (42.24)	$ (55.20)
Shares used in computing loss per basic and diluted Preferred Series C shares	4,577	20,368

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
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018
(In thousands, except share amounts)

	Convertible Preferred Stock – Series C		Common Stock		Additional Paid-	Accumulated	
	Shares	Amount	Shares	Amount	In Capital	Deficit	Total
BALANCE, JANUARY 1, 2018	36,182	$ 4	4,304,425	$ 4	$ 223,829	$ (203,957)	$ 19,880
Cumulative accounting adjustment from adoption of new standard, net of tax (Note 1)	-	-	-	-	-	(234)	(234)
Cumulative accounting adjustment from adoption of new standard, net of tax (Note 1)	-	-	-	-	2,614	(2,547)	67
Stock-based compensation	-	-	-	-	904	-	904
Conversion of convertible preferred stock into common stock	(26,214)	(3)	9,744,916	10	(7)	-	-
Sale of common stock, net of offering costs of $2,336	-	-	15,893,745	16	14,648	-	14,664
Net loss	-	-	-	-	-	(4,033)	(4,033)
BALANCE, DECEMBER 31, 2018	9,968	$ 1	29,943,086	$ 30	$ 241,988	$ (210,771)	$ 31,248
Stock-based compensation	-	-	-	-	1,195	-	1,195
Conversion of convertible preferred stock into common stock	(7,865)	-	2,923,791	3	(3)	-	-
Exercise of stock options	-	-	36,410	-	-	-	-
Issuance of restricted stock	-	-	28,986	-	-	-	-
Net loss	-	-	-	-	-	(3,790)	(3,790)
BALANCE, DECEMBER 31, 2019	2,103	$ 1	32,932,273	$ 33	$ 243,180	$ (214,561)	$ 28,653

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)

	For the Year Ended December 31,	
	2019	2018
Cash Flows From Operating Activities:		
Net loss	$ (3,790)	$ (4,033)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	4,503	5,397
Amortization of right-of-use assets	318	-
Provision for doubtful accounts	43	(30)
Gain on cancellation of distributor rights agreement	-	(11)
Impairment of lasers placed-in-service	30	194
Stock-based compensation	1,195	904
Deferred taxes	(111)	(303)
Loss on disposal of property and equipment	-	407
Amortization of deferred financing costs and debt discount	174	157
Changes in operating assets and liabilities:		
Accounts receivable	(1,036)	(222)
Inventories	(233)	215
Prepaid expenses and other assets	104	(383)
Accounts payable	116	(513)
Other accrued liabilities	634	1,006
Other liabilities	(210)	(60)
Operating lease liabilities	(241)	-
Deferred revenues	733	171
Net cash provided by operating activities	2,229	2,896
Cash Flows From Investing Activities:		
Lasers placed-in-service	(2,676)	(1,749)
Purchases of property and equipment	(115)	(13)
Payments on distributor rights liability	-	(23)
Net cash used in investing activities	(2,791)	(1,785)

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

STRATA SKIN SCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(continued)
(In thousands)

	For the Year Ended December 31,	
Cash Flows From Financing Activities:	2019	2018
Proceeds from issuance of common stock	$ -	$ 17,000
Offering costs	-	(2,336)
Repayments of long-term debt	(7,571)	(3,000)
Proceeds (payments) on notes payable	7,275	(357)
Net cash (used in) provided by financing activities	(296)	11,307
Net (decrease) increase in cash and cash equivalents and restricted cash	(858)	12,418
Cash and cash equivalents, beginning of period	16,487	4,069
Cash and cash equivalents and restricted cash, end of period	$ 15,629	$ 16,487
Cash and cash equivalents	$ 8,129	$ 16,487
Restricted cash	7,500	-
	$ 15,629	$ 16,487
Supplemental information:		
Cash paid for interest	$ 766	$ 1,009
Cash paid for income taxes	$ -	$ 17
Lease liabilities from obtaining right-of-use assets	$ 1,632	$ -

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

Note 1
The Company:

Background
STRATA Skin Sciences (the "Company") is a medical technology company in Dermatology and Plastic Surgery dedicated to developing, commercializing and marketing innovative products for the treatment of dermatologic conditions. Its products include the XTRAC® excimer laser and VTRAC® lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions.

The XTRAC is an ultraviolet light excimer laser system utilized to treat psoriasis, vitiligo and other skin diseases. The XTRAC excimer laser system first received clearance from the United States Food and Drug Administration (the "FDA") in 2000. As of December 31, 2019, there were 820 XTRAC systems placed in dermatologists' offices in the United States under the Company's recurring revenue business model. The XTRAC systems deployed under the recurring revenue model generate revenue on a per procedure basis or include a fixed payment over an agreed upon period with a capped number of treatments, which if exceeded would incur additional fees. The per-procedure charge is inclusive of the use of the system and the services provided by the Company to the customer which includes system maintenance, and other services. The VTRAC Excimer Lamp system, offered in addition to the XTRAC system internationally, provides targeted therapeutic efficacy demonstrated by excimer technology with a lamp system.

During 2017, the Company entered into an agreement to license the Nordlys product line from Ellipse A/S. In June, 2018, following the financing (see Note 3), the Company determined it would no longer market the line and wrote down all related inventory and fixed assets to the net realizable value and recorded an expense of $280 in cost of revenues.

Effective February 1, 2017, the Company entered into an exclusive OEM distribution agreement with Esthetic Education, LLC to be the exclusive marketer and seller of private label versions of the SkinStylus® MicroSystem and associated parts under the name of STRATAPEN. This three-year agreement has minimum annual sales requirements for renewal. The contract expired in January, 2020.

In July 2019, the Company signed a direct distribution agreement with its Korean distributor for a combination of direct capital sales and recurring revenues for the country of South Korea. The term is for twelve months with up to four additional twelve-month renewal terms subject to certain conditions.

***Basis of Presentation*:**

Accounting Principles
The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Principles of Consolidation
The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary in India. All significant intercompany balances and transactions have been eliminated in consolidation. In 2019 and 2018, there are no operations in the subsidiary in India.

Reclassification
Certain reclassifications from the prior year presentation have been made to conform to the current year presentation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting periods. Actual results could differ from those estimates and be based on events different from those assumptions. As of December 31, 2019, the more significant estimates include (1) revenue recognition, in regard to deferred revenues and the contract term and valuation allowances of accounts receivable, (2) the inputs used in the impairment analyses of goodwill, (3) the estimated useful lives of intangible assets and property and equipment, (4) the inputs used in determining the fair value of equity-based awards, (5) the valuation allowance related to deferred tax assets (6) the fair value of financial instruments, including derivative instruments and warrants, (7) the inventory reserves (8) state sales and use tax accruals and (9) warranty claims.

Revenue Recognition

In the Dermatology Recurring Procedures Segment the Company has two types of arrangements for its phototherapy treatment equipment as follows: (i) the Company places its lasers in a physician’s office at no charge to the physician, and generally charges the physician a fee for an agreed upon number of treatments; or (ii) the Company places its lasers in a physician’s office and charges 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.

For the purposes of U.S. GAAP only, these two types of arrangements are treated under the guidance of ASC 842, Leases. While these arrangements are not contractually operating leases, since the Company sells the physician access codes in order to operate the treatment equipment, these arrangements are similar to operating leases for accounting purposes since the Company provides the customers limited rights to use the treatment equipment and the treatment equipment resides in the physician’s office and the Company 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. The terms of the domestic arrangements are generally 36 months with automatic one-year renewals and include a termination clause that can be affected at any time by either party with 30 to 60 day notice. Amounts paid are generally non-refundable. 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 ratably 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, through its Korean distributor, the Company sells access codes for a fixed amount on a monthly basis to end user customers 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. Pre-paid amounts are recorded in deferred revenue and recognized as revenue over the lease term in the patterns described above. Under both methods, 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.

In the Dermatology Procedures Equipment segment the Company sells its products internationally through distributors and domestically, directly to a physician. For the product sales, the Company recognizes revenues 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.

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 but excludes any equipment accounted for as leases. As of December 31, 2019, and 2018, the aggregate amount of the transaction price allocated to remaining performance obligations was $324 and $429, respectively, and the Company expects to recognize $209 and $162, respectively, of the remaining performance obligations within one year and the remainder over one to three years. Contract assets primarily relate to the Company's rights to consideration for work completed in relation to its services performed but not billed at the reporting date. The contract assets are transferred to receivables when the rights become unconditional. Currently, the Company does not have any contract assets which have not transferred to a receivable. Contract liabilities primarily relate to extended warranties 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, 2019, and 2018, the $209 and $162 of short-term contract liabilities, respectively, is presented as deferred revenues and the $115 and $267 of long-term contract liabilities, respectively, is presented within Other Liabilities on the Consolidated Balance Sheet, respectively. For the year ended December 31, 2019, and 2018, the Company recognized $155 and $58, respectively, as revenue from amounts classified as contract liabilities (i.e. deferred revenues) as of December 31, 2018, and 2017.

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

The Company records co-pay reimbursements made to patients receiving laser treatments as a reduction of revenue. For the years ended December 31, 2019, and 2018, the Company recorded such reimbursements in the amounts of $779 and $579, respectively.

Cash and Cash Equivalents and Restricted Cash

Cash and cash equivalents consisted of cash and money market accounts at December 31, 2019, and 2018. The Company invests its cash in highly liquid short-term investments and credit card transactions with settlement terms of less than five days. The Company considers short-term investments that are purchased with an original maturity of three months or less to be cash equivalents. Proceeds due from credit card transactions were $21 and $6 as of December 31, 2019, and 2018, respectively. In connection with the Company's note payable, the Company pledged the proceeds of a time-deposit account in the amount of the loan and interest and recorded the cash security as restricted cash.

Accounts Receivable, net

The majority of the Company's accounts receivable are due from physicians, distributors (international) and other entities in the medical field. Accounts receivable are most often due within 30 to 90 days and are stated at amounts due from customers net of an allowance for doubtful accounts. Accounts outstanding longer than the contractual payment terms are considered past due. The Company determines its allowance for doubtful accounts by considering a number of factors, including the length of time trade accounts receivable are past due, the Company's previous loss history, the customer's current ability to pay its obligation to the Company and available information about their credit risk, and the condition of the general economy and the industry as a whole. The Company writes off accounts receivable when they are considered uncollectible, and payments subsequently received on such receivables are credited to the bad debt expense. The Company does not recognize interest accruing on accounts receivable past due. The allowance for doubtful accounts was $184 and $141 at December 31, 2019, and 2018, respectively.

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. As of December 31, 2019, and 2018, reserves on inventory were $225 and $308, respectively.

Property, Equipment and Depreciation

Property and equipment are recorded at cost, net of accumulated depreciation and amortization. Excimer lasers-in-service are depreciated on a straight-line basis over the estimated useful life of five years. For other property and equipment, depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, primarily three to seven years for computer hardware and software, furniture and fixtures, and machinery and equipment. Leasehold improvements are amortized over the lesser of the useful lives or lease terms. Expenditures for major renewals and betterments to property and equipment are capitalized, while expenditures for maintenance and repairs are charged as an expense as incurred. Upon retirement or disposition, the applicable property amounts are deducted from the accounts and any gain or loss is recorded in the consolidated statements of operations. Useful lives are determined based upon an estimate of either physical or economic obsolescence or both.

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 ten years.

Accounting for the Impairment of Goodwill

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. The Company evaluates the carrying value of goodwill annually in December of each year in connection with the annual budgeting and forecast process and also between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the reporting unit to which goodwill was allocated to below its carrying amount. Such circumstances could include, but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, or (3) an adverse action or assessment by a regulator. When evaluating goodwill for impairment, the Company may first perform an assessment qualitatively whether it is more likely than not that a reporting unit's carrying amount exceeds its fair value. Under Accounting Standards Update (“ASU”) 2017-04, “Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment,” Step 2 from the goodwill impairment test has been eliminated and goodwill impairment is measured as the excess of the carrying amount of the reporting unit over its fair value. Early application is permitted. As the Company has not identified a goodwill impairment loss, currently this guidance does not have an impact on the Company’s financial statements but could have an effect in the event of a goodwill impairment. The Company bypassed the qualitative assessment and did a quantitative assessment by comparing the fair value of a reporting unit with its carrying amount. No goodwill impairment was identified in the years ended December 31, 2019, and 2018.

Impairment of Long-Lived Assets and Intangibles

Long-lived assets, such as property and equipment, right-of-use assets and definite-lived intangibles subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. 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.

Functional Currency

The currency of the primary economic environment in which the operations of the Company are conducted is the U.S. dollar ("$" or "dollars"). Substantially all of the Company's revenues are derived in dollars or in other currencies linked to the dollar. Purchases of most materials and components are carried out in, or linked to the dollar.

For foreign currency transactions, the exchange rates applicable to the relevant transaction dates are used. Transaction gains or losses arising from changes in the exchange rates are recorded in financing income or expenses.

Fair Value Measurements

The Company measures and discloses fair value in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification 820, *Fair Value Measurements and Disclosures* (“ASC Topic 820”). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions there exists a three-tier fair-value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 – unadjusted quoted prices are available in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.
- Level 2 – pricing inputs are other than quoted prices in active markets that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

(In thousands, except share, per share amounts and number of lasers)

- Level 3 – pricing inputs are unobservable for the asset or liability and only used when there is little, if any, market activity for the asset or liability at the measurement date. The inputs into the determination of fair value require significant management judgment or estimation. Fair value is determined using comparable market transactions and other valuation methodologies, adjusted as appropriate for liquidity, credit, market and/or other risk factors.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The fair value of cash and cash equivalents and restricted cash are based on their respective demand value, which are equal to the carrying value. The fair value of derivative warrant liability is estimated using option pricing models that are based on the fair value of the Company's common stock as well as assumptions for volatility, remaining expected life, and the risk-free interest rate. The derivative warrant liability is the only recurring Level 3 fair value measure. The carrying value of all other short-term monetary assets and liabilities is estimated to be approximate to their fair value due to the short-term nature of these instruments. As of December 31, 2018, the Company assessed its long-term debt (including the current portion) and determined that the fair value of total debt approximated its book value due to the interest rate on the debt approximating market rates. At December 31, 2019, the Company repaid its long-term debt and now has a short-term note payable. The carrying value of this note is estimated to approximate its fair value due to its short-term nature.

The Company's warrant liabilities were recorded at their fair value using binomial and Black-Scholes methods and continued- to be recorded at their respective fair value at each subsequent balance sheet date until such terms expire. (See *Note 12*, **Warrants**, for additional discussion).

Accrued Warranty Costs

The Company offers a standard warranty on product sales generally for a one to two-year period, however, the Company has offered longer warranty periods, ranging from three to four years, in order to meet competition or meet customer demands. The Company provides for the estimated cost of the future warranty claims on the date the product is sold. Total accrued warranty is included in ***Other Accrued Liabilities*** and ***Other liabilities*** on the consolidated balance sheets. The activity in the warranty accrual during the years ended December 31, 2019, and 2018, is summarized as follows:

	December 31,	
	2019	2018
Accrual at beginning of year	$ 238	$ 178
Additions charged to warranty expense	222	291
Expiring warranties/claims satisfied	(228)	(231)
Total	232	238
Less: current portion	(170)	(156)
Total long-term accrued warranty costs	$ 62	$ 82

Product Development Costs
Costs of research, new product development and product redesign are charged to expenses as incurred in engineering and product development in the accompanying consolidated statements of operations. The Company incurred $1,002 and $1,065 in engineering and product development costs for the years ended December 31, 2019, and 2018, respectively.

Advertising Costs
Advertising costs are charged to expenses as incurred. Advertising expenses amounted to approximately $1,936 and $1,202 for the years ended December 31, 2019, and 2018, respectively.

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 accounts for uncertain tax positions in accordance with an amendment to ASC Topic 740-10, *Income Taxes* (*Accounting for Uncertainty in Income Taxes)*, which clarified the accounting for uncertainty in tax positions. This amendment provides that the tax effects from an uncertain tax position can be recognized in the financial statements 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.

Concentration of Credit Risks
Financial instruments which subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, restricted cash and accounts receivable. The Company deposits cash and cash equivalents and restricted cash in major financial institutions in the US which, at times exceeds Federal Deposit Insurance Corporation and Securities Investor Protection Corporation limits. The Company performs periodic evaluations of the relative credit standing of these institutions. The Company is of the opinion that the credit risk in respect of these balances is immaterial. In addition, the Company performs periodic credit evaluation and establishes an allowance for doubtful accounts based upon factors surrounding the credit risk of customers. (See also ***Accounts receivable*** above).

With the exception of the Company’s international distributor, as described in *Note 18*, **Significant Customer Concentrations**, the balance of the Company’s trade receivables does not represent a substantial concentration of credit risk. Most of the Company’s sales are generated in North America, to a large number of customers.

Management periodically evaluates the collectability of the trade receivables to determine the amounts that are doubtful of collection and determine a proper allowance for doubtful accounts.

Earnings Per Share
The Company calculates loss per common share and Preferred Series C share in accordance with ASC 260, *Earnings per Share*. Under ASC 260, basic loss per common share and Preferred Series C share is calculated by dividing net loss attributable to common shares and Preferred Series C shares by the weighted-average number of common shares and Preferred Series C shares outstanding during the reporting period and excludes dilution for potentially dilutive securities. Diluted loss per common share and Preferred Series C share gives effect to dilutive options, warrants and other potential common shares outstanding during the period.

(In thousands, except share, per share amounts and number of lasers)

Shares of Company's Series C Convertible Preferred Stock are subordinate to all other securities at the same subordination level as common stock and they participate in all dividends and distributions declared or paid with respect to common stock of the Company, on an as-converted basis. Therefore, the Series C Convertible Preferred Stock meet the definition of common stock under ASC 260. Earnings per share is presented for each class of security meeting the definition of common stock. The loss is allocated to each class of security meeting the definition of common stock based on their contractual terms.

The following table presents the calculation of basic and diluted loss per share by each class of security for the years ended December 31, 2019, and 2018:

	Year ended December 31, 2019		Year ended December 31, 2018	
	Common Stock	Series C Convertible Preferred Stock	Common Stock	Series C Convertible Preferred Stock
Loss attributable to each class	$ (3,597)	$ (193)	$ (2,909)	$ (1,124)
Weighted average number of shares outstanding during the period	31,978,665	4,577	19,589,031	20,368
Basic and Diluted loss per share	$ (0.11)	$ (42.24)	$ (0.15)	$ (55.20)

The Company considered Series C Preferred Stock and 403,090 warrants issued on October 31, 2013 and February 14, 2014, to be participating securities in the presentation of earnings per share. However, the warrants are excluded from the calculation of earnings per share in periods of losses as the warrant holders do not have an obligation to fund such losses. The above referenced warrants expired on April 30, 2019 and February 14, 2019.

For the years ended December 31, 2019, and 2018, diluted loss per common share and Series C Convertible Preferred Stock share is equal to the basic loss per common share and Series C Convertible Preferred Stock share, respectively, since all potentially dilutive securities are anti-dilutive.

The following common stock equivalents outstanding during the years ended December 31, 2019, and 2018, have been excluded from the loss per share calculation as their inclusion would have been anti-dilutive:

	Year Ended December 31,	
	2019	2018
Common stock purchase warrants	1,517,528	2,397,166
Restricted stock units	128,417	79,068
Common stock options	4,235,451	3,188,897
Total	5,881,396	5,665,131

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718, *Compensation – Stock Compensation*. Under the fair value recognition provision of this statement, share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense over the requisite service period of the stock award on a straight-line basis. Forfeitures are recognized when they occur. Performance-based awards are recognized only when it is probable that the vesting conditions will be met. There were no performance awards granted in 2019 or 2018.

Accounting Pronouncements Recently Adopted

In February 2016 the FASB issued ASU 2016-02, "Leases" (Topic 842) ("ASU 2016-02"), which will require lessees to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current U.S. GAAP, the recognition, measurement and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. However, unlike current U.S. GAAP, which requires only capital leases to be recognized on the balance sheet, the new guidance requires both types of leases to be recognized on the balance sheet. The ASU is effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted. In August 2018 the FASB issued ASU No. 2018-11, "Leases (Topic 842: Targeted Improvements") which permits adoption of the guidance in ASU 2016-02 using either a modified retrospective transition, requiring application at the beginning of the earliest comparative period presented or a transition method whereby companies could continue to apply existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative-effect adjustment in the period of adoption rather than in the earliest period presented without adjusting historical financial statements.

The Company used the modified retrospective transition approach to ASU No. 2018-11 and applied the new lease requirements through a cumulative-effect adjustment in the period of adoption. The new standard provides a number of optional practical expedients in transition. We elected the package of practical expedients, which permits us not to reassess, under the new standard, our prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us. This accounting standard did not have a material impact on our debt covenants. The Company has completed an evaluation of ASU 2016-02, including a review of our leases and other contracts for potential embedded leasing arrangements and has recognized approximately $848 in right-of-use assets and lease liabilities in the balance sheet as of January 1, 2019. There was no impact on the Company's revenue recognition under ASC 842.

In July 2017 the FASB issued a two-part ASU 2017-11, "(Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-Controlling Interests with a Scope Exception." For public business entities the amendments in Part I of ASU 2017-11 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. The Company previously adopted this ASU on October 1, 2018, and recorded an adjustment for the adoption of a new accounting pronouncement of $67 as an adjustment to warrant liability, $2,547 as an adjustment to accumulated deficit and $2,614 as an adjustment to additional paid-in-capital as of the beginning of the fiscal year in the year of adoption on January 1, 2018.

In May 2014 the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. ASU 2014-09 also requires entities to disclose sufficient information, both quantitative and qualitative, to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The Company has adopted this ASU effective January 1, 2018, using the modified retrospective method to those contracts not completed at the application date with a cumulative adjustment that increased its accumulated deficit by approximately $234.

The cumulative adjustment primarily related to the promise to provide service type warranties related to sales of dermatology procedures equipment. A portion of the transaction price of equipment sold with these service type warranties has been allocated to such performance obligation based on their stand-alone selling price, and the Company began to recognize revenue from these service type warranties ratably over the warranty term. Under current guidance, only separately priced extended warranties are required to be accounted for as separate elements and be recognized over the warranty term. The method used to estimate stand-alone selling price is the price observed in transactions where the customer is charged a discrete price for the extended warranty. Other than the above change related to warranties, the adoption of this standard did not have a material impact on the Company's financial condition or results of operations.

In June 2018 the FASB issued ASU No. 2018-07, "Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," with the objective of simplifying several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The provisions of this update are effective for fiscal years beginning after December 15, 2018, including interim periods within that year. The adoption of ASU No. 2018-07 on January 1, 2019, did not have a material effect on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The new guidance eliminated Step 2 from the goodwill impairment test which was required in computing the implied fair value of goodwill. Instead, under the new amendments, an entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. If applicable, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The amendments in this guidance are effective for public business entities for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2019 with early adoption permitted after January 1, 2017. As the Company has not identified a goodwill impairment loss, currently this guidance does not have an impact on the Company's consolidated financial statements, but could have an impact in the event of a goodwill impairment.

In August 2018 the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement. The new guidance improves and clarifies the fair value measurement disclosure requirement of ASC 820. The new disclosure requirements include the changes in unrealized gains or losses included in other comprehensive income for recurring Level 3 fair value measurement held at the end of the reporting period and the explicit requirement to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The other provisions of ASU 2018-13 also include eliminated and modified disclosure requirements. The guidance is effective for fiscal years beginning after December 15, 2019, with early adoption permitted, including in an interim period for which financial statements have not been issued or made available for issuance. The Company has evaluated the impact of adoption of this ASU and determined that it will have no significant impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 eliminated certain exceptions and changed guidance on other matters. The exceptions relate to the allocation of income taxes in separate company financial statements, tax accounting for equity method investments and accounting for income taxes when the interim period year-to-date loss exceeds the anticipated full year loss. Changes relate to the accounting for franchise taxes that are income-based and non-income-based, determining if a step up in tax basis is part of a business combination or if it is a separate transaction, when enacted tax law changes should be included in the annual effective tax rate computation, and the allocation of taxes in separate company financial statements to a legal entity that is not subject to income tax. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December15, 2020, with early adoption permitted. The Company is currently evaluating the potential impact but does not believe there will be an impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

Note 2
Liquidity and Capital Resources

The Company has experienced recurring operating losses although positive operating cash flow was generated in both 2019 and 2018. Historically, the Company has been dependent on raising capital from the sale of securities in order to continue to operate and to meet our obligations in the ordinary course of business. Management believes that our cash and cash equivalents, combined with the anticipated revenues from the sale of the Company's products will be sufficient to satisfy our working capital needs, capital asset purchases, outstanding commitments and other liquidity requirements associated with the Company's existing operations through the next 12 months following the issuance of these Company's consolidated financial statements.

Equity Financing
On March 30, 2018, the Company entered into multiple agreements in order to obtain $17,000 of equity financing (the "Financing") from the following sources:

- On March 30, 2018, the Company entered into a Stock Purchase Agreement (the "Accelmed SPA") and a Registration Rights Agreement with Accelmed Growth Partners L.P. ("Accelmed") investing $13,000 into the Company at a price per share of $1.08; upon closing Accelmed received 12,037,037 shares of its common stock.
- In connection with the Accelmed investment, the Company entered into two separate stock purchase agreements, each for approximately $1,000 with its then current shareholders, Broadfin Capital ("Broadfin") and Sabby Management ("Sabby"). Upon closing of these transactions, each of Sabby and Broadfin received 925,926 shares of the Company's common stock at a price per share of $1.08.
- Two separate subscription agreements were also executed on in connection with the Accelmed investment: (i) a subscription agreement with Gohan Investments, Ltd. for $1,000 to purchase 925,926 shares of the Company's common stock at $1.08 per share; and (ii) a subscription agreement with Dr. Dolev Rafaeli, the new CEO of the Company effective May 29, 2018, for $1,000 to purchase 925,926 shares of the Company's common stock at $1.08 per share.

The Company incurred $2,336 of costs related to the equity financing during the year ended December 31, 2018, which have been offset against the offering proceeds in the accompanying financial statements.

In further consideration of entering into their respective stock purchase agreements ("SPA"), Sabby and Broadfin each entered into separate agreements restricting their abilities to sell their holdings (the "Leak-Out Agreements"). Under the terms of each of the respective Leak-Out Agreements, the stockholder has agreed that from the later of (a) the date that the approval by the shareholders of the transactions is deemed effective and (b) the closing of the transactions contemplated pursuant to the SPA, the stockholder shall not sell dispose or otherwise transfer, directly or indirectly, (including, without limitation, any sales, short sales, swaps or any derivative transactions that would be

(In thousands, except share, per share amounts and number of lasers)

equivalent to any sales or short positions) any shares of Common Stock of the Company held by the Stockholder on the date hereof or issuable to the Stockholder upon conversion of shares of the Company's Preferred Stock held by the Stockholder on the date hereof, (a) if prior to April 1, 2019, at a price per Company Share less than $1.296, subject to adjustment for reverse and forward stock splits and the like, or (b) thereafter, at a price per share reflecting less than the price set forth on the schedule in the Leak-Out Agreements subject to adjustment for reverse and forward stock splits and the like, unless, (1) in the case of either clause (a) or (b), otherwise approved by the Company's Board of Directors, (2) in the case of clause (b), under a shelf prospectus or such other controlled offering as may be agreed to by the Principal Stockholders (as defined in the Stock Purchase Agreement) or (3) in the case of either clause (a) or (b), in a sale pursuant to which any other stockholder(s) of the Company are offered the same terms of sale, including in a merger, consolidation, transfer or conversion involving the Company or any of its subsidiaries.

In addition, Sabby and Broadfin delivered to the Company a voting undertaking obligating Sabby and Broadfin to increase their respective "blocker" to 9.99% prior to the record date for the meeting of the shareholders.

On May 23, 2018, the Company held a special meeting of stockholders where the stockholders approved pursuant to Nasdaq Listing Rules 5635(b) and (d), the issuance of an aggregate of 15,740,741 shares of the Company's common stock pursuant to the Financing plus all additional shares that may be issued pursuant to the Retained Risk Provisions, as defined in the purchase agreements.

The investors in the Financing may receive additional shares, in the event of certain contingencies, as described in the SPA's. 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 are additional contingencies included in the SPA's that the Company has determined are not probable or estimable at this time.

In connection with the SPA's, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Investors to prepare and file with the SEC a registration statement covering the shares of common stock issued in the Financing. The Company filed a registration statement on Form S-3 which became effective on September 24, 2018.

Note 3
Revenue:

The following table presents the Company's revenue disaggregated by geographical region for the years ended December 31, 2019, and 2018. Domestic refers to revenue from customers based in the United States, and substantially all foreign revenue is derived from dermatology procedures equipment sales to the Company's international master distributor for physicians based primarily in Asia.

	Year Ended December 31, 2019		
	Dermatology Recurring Procedures	Dermatology Procedures Equipment	TOTAL
Domestic	$ 23,645	$ 1,243	$ 24,888
Foreign	68	6,630	6,698
Total	$ 23,713	$ 7,873	$ 31,586

(In thousands, except share, per share amounts and number of lasers)

	Year Ended December 31, 2018		
	Dermatology Recurring Procedures	Dermatology Procedures Equipment	TOTAL
Domestic	$ 21,053	$ 2,026	$ 23,079
Foreign	-	6,776	6,776
Total	$ 21,053	$ 8,802	$ 29,855

The following table summarizes the Company's expected future undiscounted fixed treatment code payments from international recurring revenue customers as of December 31,

2020	$ 311
2021	233
2022	233
2023	180
2024	67
Total	$ 1,024

Note 4
Inventories:

	December 31, 2019	December 31, 2018
Raw materials and work in process	$ 2,651	$ 2,442
Finished goods	376	352
	$ 3,027	$ 2,794

Work-in-process is immaterial, given the Company's typically short manufacturing cycle, and therefore is included in with raw materials.

Note 5
Property and Equipment, net:

	December 31, 2019	December 31, 2018
Lasers placed-in-service	$ 20,925	$ 18,515
Equipment, computer hardware and software	146	168
Furniture and fixtures	234	124
Leasehold improvements	26	26
	21,331	18,833
Accumulated depreciation and amortization	(15,962)	(13,532)
Property and equipment, net	$ 5,369	$ 5,301

Depreciation and related amortization expense was $2,693and $3,563 for the years ended December 31, 2019, and 2018, respectively.

During the year ended December 31, 2018, the Company recorded an impairment loss of fixed assets of $194 to cost of revenues as a result of the Company no longer marketing the Nordlys product line. In addition, the Company recorded $407 in other disposals for the year ended December 31, 2018.

(In thousands, except share, per share amounts and number of lasers)

Note 6
Intangible Assets, net:

Set forth below is a detailed listing of definite-lived intangible assets as of:

	December 31,			
	2019			2018
	Balance	Accumulated Amortization	Intangible assets, net	Intangible assets, net
Core technology	$ 5,700	$ 2,565	$ 3,135	$ 3,705
Product technology	2,000	1,800	200	600
Customer relationships	6,900	3,105	3,795	4,485
Tradenames	1,500	675	825	975
	$ 16,100	$ 8,145	$ 7,955	$ 9,765

Related amortization expense was $1,810 and $1,834 for the years ended December 31, 2019, and 2018, respectively. Total accumulated amortization at December 31, 2018 was $6,335. Intangible assets consist of core technology, product technology, customer relationships, trademark 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 ten years.

During 2018, related to the discontinuance of the Nordlys product line, the Company wrote off distribution rights of $286 and accumulated amortization of $60. In addition, the Company wrote off distribution liabilities of $237 as a result of the termination of the agreements on May 31, 2018. The net value written off of $11 was recorded in selling and marketing expense.

Estimated amortization expense for the above amortizable intangible assets for the future periods is as follows:

2020	$ 1,610
2021	1,410
2022	1,410
2023	1,410
2024	1,410
Thereafter	705
Total	$ 7,955

Note 7
Goodwill:

Goodwill reflects the amount of the acquisition price in excess of the fair values assigned to identifiable tangible and intangible assets and assumed liabilities. Goodwill is not amortized, but is reviewed annually for impairment. Goodwill was recorded on the acquisition of the XTRAC and VTRAC businesses on June 22, 2015, as the purchase price exceeded the fair value of the identifiable net assets of the business. The balance of goodwill at December 31, 2019, and 2018 consisted of the following:

Dermatology Recurring Procedures segment	$ 7,958
Dermatology Procedures Equipment segment	845
Total	$ 8,803

The Company has incurred no impairment of goodwill as of December 31, 2019 and 2018.

(In thousands, except share, per share amounts and number of lasers)

Note 8
Other Accrued Liabilities:

	December 31, 2019	December 31, 2018
Accrued warranty, current, see Note 1	$ 170	$ 156
Accrued compensation, including commissions and vacation	1,193	1,275
Accrued state sales use and other taxes	3,193	2,719
Accrued professional fees and other accrued liabilities	578	350
Total other accrued liabilities	$ 5,134	$ 4,500

In the ordinary course of business, the Company is, from time to time, subject to audits performed by state taxing authorities. These actions and proceedings are generally based on the position that the arrangements entered into by the Company are subject to sales and use tax rather than exempt from tax under applicable law. The Company uses estimates when accruing its sales and use tax liability. All of the Company's tax positions are subject to audit. One state has assessed the Company an amount of $801 for the period from March 2014 through August 2017. The Company has declined an informal offer to settle at a substantially lower amount and is currently in that jurisdiction's administrative process of appeal. A second jurisdiction has made an initial preliminary assessment of $724 from June 2015 through March 2018 plus interest of $171 through April 2020. 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 does not prevail, the Company may be subject to sales taxes in those particular states for previous years and in the future, plus potential interest and penalties for failure to pay such taxes.

The Company believes its state sales and use tax accruals have 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 are 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.

The Company records state sales tax collected and remitted for its customers on 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 are recorded in general and administrative expenses on the consolidated statements of operations.

Note 9
Note Payable

On December 30, 2019, the Company closed on a $7,275 loan with a commercial bank pursuant to a one-year Fixed Rate – Term Promissory Note (the "Note"). The Company's obligations under the Note are secured by an Assignment and Pledge of Time Deposit (the "Agreement"), under which the Company has pledged to the commercial bank the proceeds of a time deposit account in the amount of the loan and recorded the time deposit and interest as restricted cash on the balance sheet. The principal is due on December 30, 2020 with no penalties for prepayments. The interest rate is fixed at 2.79%. The secured time deposit has a fixed interest rate of 1.79%. The Company fully repaid (including payment of termination and exit fees) its existing long-term debt credit facility with Midcap Financial Trust ("MidCap"). The transaction was accounted for as a debt extinguishment. See Note 10 **Long-term Debt** for further discussion on the extinguishment.

Note 10
Long-term Debt:

Term-Note Credit Facility
On December 30, 2015, the Company entered into a $12,000 credit facility pursuant to a Credit and Security Agreement (the "Credit Agreement") and related financing documents with MidCap and the lenders listed therein. Under the Credit Agreement, the credit facility may be drawn down in two tranches, the first of which was drawn for $10,500 on December 30, 2015. The second tranche was drawn for $1,500 on January 29, 2016. The maturity date of the credit facility was December 1, 2020. The Company's obligations under the credit facility were secured by a first priority lien on all the Company's assets. This credit facility had an interest rate of one-month LIBOR plus 8.25% and included both financial and non-financial covenants, including a minimum net revenue covenant. On November 10, 2017, the minimum net revenue covenant was amended prospectively and there was an increase in the exit fee. Additionally, on November 10, 2017, the Company entered into an amendment to modify the principal payments including a period of six months where there are no principal payments due.

On March 26, 2018, the Company entered into a Third Amendment to the Credit Agreement with MidCap. For the period beginning on the closing date of the loan and ending on January 31, 2018, the gross revenue in accordance with U.S. GAAP for the twelve-month period ending on the last day of the most recently completed calendar month was amended to be less than the minimum amount on the Covenant Schedule, as defined in the Credit Agreement. This amendment waived the event of default related to the revenue covenant for the period ending February 2018. This amendment also amended the monthly net revenue covenant.

On May 29, 2018, the Company entered into a Fourth Amendment to Credit Agreement (the “Amendment”), pursuant to which the Company repaid $3,000 in principal of then existing $10,571 credit facility. The terms of the credit facility were amended to impose less restrictive covenants and lower prepayment fees for the Company and extended the maturity date to May 2022. The Amendment modified the principal payments including a period of 18 months where there are no principal payments due. The interest rate on the credit facility is one-month LIBOR plus 7.25%. Principal payments beginning December 2019 were $252 plus interest per month. The Company was in compliance with all covenants as of December 31, 2018. On April 30, July 15, August 26, and October 15, 2019, the Company received waivers from Midcap as administrative agent for the lenders who are party to the Agreement, wherein the lenders waived the Company’s compliance with the obligation to deliver audited financial statements within 120 days of year-end pursuant to the Credit Agreement. The waivers were effective through November 7, 2019. The Company delivered the audited financial statements on or about October 29, 2019 to cure the event of default. The effective interest rate was 9.6% as of December 31, 2018.

These amendments had been accounted for as debt modifications as the present value of the cash flows changed by less than 10%.

This Term-Note Credit Facility was fully repaid in connection with the execution of a Fixed Rate-Promissory Note on December 30, 2019. The Company accounted for the repayment as an extinguishment of debt and recorded a loss of $414 in the consolidated statements of operations during the year ended December 31, 2019.

Note 11
Commitments and Contingencies:

Leases
The Company recognizes right-of-use assets (“ROU Assets”) and operating lease liabilities (“Lease Liabilities”) when it obtains the right to control an asset under a leasing arrangement with an initial term greater than twelve 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.

(In thousands, except share, per share amounts and number of lasers)

All of the Company's leasing arrangements are classified as operating leases with remaining lease terms ranging from 1 to 5 years, and one facility lease has a renewal option for two years. Renewal options have been excluded from the determination of the lease term as they are not reasonably certain of exercise. On May 1, 2019, the Company entered into an addendum with FR National Life, LLC for the Carlsbad facility for five years which began on October 1, 2019. Total rent expense for the year ended December 31, 2018 was, $440.

Operating lease costs were $448 for the year ended December 31, 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $371 for year ended December 31, 2019. As of December 31, 2019, the incremental borrowing rate was 9.76% and the weighted average remaining lease term was 4.1 years. The following table summarizes the Company’s operating lease maturities as of December 31, 2019:

For the year ending December 31,	
2020	$ 436
2021	456
2022	371
2023	242
2024	186
Total remaining lease payments	1,691
Less: imputed interest	(300)
Total lease liabilities	$ 1,391

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.

For contingencies related to sales and use taxes, *see Note 8*.

Litigation
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.

Note 12
Warrants:

The Company accounts for warrants that require net cash settlement upon change of control of the Company as liabilities instead of equity. There were 403,090 of such warrants with an exercise price of $3.75 per share which expired on February 5, 2019 and April 30, 2019.

The Company recognized these liabilities at the fair value on each reporting date. The Company computed the value of the warrants using the binomial and Black-Scholes methods. A summary of quantitative information with respect to the valuation methodology and significant unobservable inputs used for the Company’s warrant liability that is categorized within Level 3 of the fair value hierarchy as of December 31, 2018 is as follows:

(In thousands, except share, per share amounts and number of lasers)

	December 31, 2018
Number of shares underlying the warrants	403,090
Stock price	$ 2.60
Volatility	56.97%
Risk-free interest rate	2.63%
Expected dividend yield	0%
Expected warrant life	0.12 – 0.35 years

The Company's level 3 fair value measurements as of December 31, 2018 were as follows:

	Fair Value as of December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Warrant liability	$ -	$ -	$ -	$ -

Recurring level 3 Activity and Recalculation

The Company adopted ASU 2017-11 on October 1, 2018, and reclassified the value of the warrants with down round provisions to equity on January 1, 2018. There were no gains or losses in fair value during the years ended December 31, 2019, and 2018 and the beginning and ending balance for the liabilities measured at fair value using significant unobservable inputs (level 3) were de minimis at December 31, 2018. These warrants expired in 2019.

Number of Warrants Subject to Remeasurement at December 31, 2018:

	December 31, 2018
October 31, 2013	137,143
February 5, 2014	265,947
Total	403,090

Note 13

Stockholders' Equity:

Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock with a par value of $0.10 per share 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. The Series C Convertible Preferred Stock have the same level of subordination as common stock. 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 for a total of approximately 15,049,000 shares of common stock. There were 2,103 and 9,968 shares of Series C Convertible Preferred Stock issued and outstanding on December 31, 2019, and 2018, respectively. For the years ended December 31, 2019, and 2018, investors converted shares of Series C Preferred Stock into 2,923,791 and 9,744,916 shares of common stock, respectively.

(In thousands, except share, per share amounts and number of lasers)

Common Stock and Warrants

The Company is authorized to issue 150,000,000 shares of common stock with a par value of $0.001 per share. There were 32,932,273 and 29,943,086 shares of common stock issued and outstanding at December 31, 2019, and 2018, respectively.

Outstanding common stock warrants at December 31, 2019 consist of the following:

Issue Date	Expiration Date	Total Warrants	Exercise Price
June 22, 2015	June 22, 2020	600,000	$ 3.75
December 30, 2015	December 30, 2020	130,089	$ 5.65
January 29, 2016	January 29, 2021	19,812	$ 5.30
		749,901	

Note 14

Stock-based compensation:

Stock Options

On October 27, 2016, the Company's stockholders approved the Company's adoption of the new 2016 Omnibus Incentive Stock Plan ("2016 Plan") having 2,058,880 shares available for issuance in respect of awards made thereunder. The Company terminated the 2013 Stock Incentive Plan in October 2016. On May 29, 2018, the Company's stockholders approved the Company's amendment to the 2016 Plan to increase the number of the Company's common stock available for grants under the plan by 3,134,365. As of December 31, 2019, the aggregate number of shares of common stock remaining available for issuance for awards under the 2016 Plan totaled 432,774.

A summary of option transactions for all of the Company's stock options during the years ended December 31, 2019, and 2018 follows:

	Number of Stock Options	Weighted Average Exercise Price
Outstanding at January 1, 2018	865,722	$ 4.74
Granted	3,770,877	1.48
Exercised	-	-
Expired/forfeited	(293,834)	2.80
Outstanding at December 31, 2018	4,342,765	2.02
Granted	875,000	2.46
Exercised	(86,250)	1.74
Expired/forfeited	(223,477)	6.43
Outstanding at December 31, 2019	4,908,038	$ 1.90
Exercisable at December 31, 2019	1,904,526	$ 2.04
Options expected to vest at December 31, 2019	3,003,512	$ 1.82

The outstanding options at December 31, 2019, have a range of exercise prices and associated weighted remaining contractual life and weighted average exercise price, as follows:

(In thousands, except share, per share amounts and number of lasers)

Options Range of Exercise Prices	Outstanding Number of Shares	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Exercisable Number of Shares	Exercisable Weighted Average Exercise Price
$ 1.11 - $5.00	4,741,877	8.6	$ 1.68	1,738,465	$ 1.46
$ 5.01 - $10.00	160,000	5.6	6.15	160,000	6.15
$ 10.01 - $181.00	6,161	3.4	62.03	6,061	61.65
Total	4,908,038	8.5	$ 1.90	1,904,526	$ 2.04

The weighted average remaining contractual life of exercisable options was 8.03 years and 5.80 years at December 31, 2019, and 2018, respectively.

The share price as of December 31, 2019, was $2.08 and the aggregate intrinsic value for options outstanding and exercisable was $2,300 and $1,156, respectively. The intrinsic value of the options that were exercised was $109 during the year ended December 31, 2019. The share price for December 31, 2018, was $2.60 and the intrinsic value for options outstanding and exercisable was $4,355 and $694, respectively.

Stock awards under the Company's stock option plans have been granted with exercise prices that are no less than the market value of the stock on the date of the grant. Options granted under the plans are generally time-based or performance-based options and vesting varies accordingly (see below for specific vesting conditions). There were no performance-based options granted in 2019 or 2018. Options under the plans expire up to a maximum of ten years from the date of grant. The fair value of each option award granted during the period is estimated on the date of grant using the Black-Scholes option valuation model and assumptions as noted in the following table:

	Years Ended December 31,	
	2019	2018
Risk-free interest rate	1.66%	2.56-2.89%
Volatility	71%	52%-55%
Expected dividend yield	0%	0%
Expected life	6.0 years	6.0 years

The expected life of the 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. Volatility is based on Company historical volatility and comparable companies' historical stock prices matching the expected term of the award. The risk-free rate is based on rates provided by the U.S. Treasury with a term equal to the expected life of the option. The Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

On March 30, 2018, the Company issued options to purchase 1,557,628 shares of common stock to its then Interim, now current Chief Executive Officer with a strike price of $1.12 per share. The options vest over three years and expire ten years from the date of grant. The aggregate fair value of the options granted was $950.

On May 23, 2018, the Company issued options to purchase 1,413,249 shares of common stock to its Chief Executive Officer with a strike price of $1.66 per share. The options vest over three years and expire ten years from the date of grant. The aggregate fair value of the options granted was $1,273.

There were additional grants made to other management members after the Financing, totaling 800,000 at strike prices ranging from $1.66 to $1.93. The options vest over three years and expire ten years from the date of grant. The aggregate fair value of the options granted was $801.

(In thousands, except share, per share amounts and number of lasers)

For the year ended December 31, 2019, 86,250 of options were exercised at a weighted average exercise price of $1.74 which resulted in the issuance of 36,410 of shares of common stock.

On November 21, 2019, the Company granted options to purchase 300,000 shares of common stock to its Chief Executive Officer, 150,000 shares of common stock to its Chief Financial Officer and 425,000 in additional grants to management at a strike price of $2.46. The options vest over three years and expire ten years from the date of grant. The aggregate fair value of the options granted was $1,361.

The following table summarizes the Company's unvested stock option activity:

	Options	Weighted Average Grant Date Fair Value
Unvested balance as of January 1, 2018	322,817	$ 0.65
Granted	3,770,877	0.80
Vested	(488,407)	0.51
Forfeited/expired	(210,819)	0.51
Unvested balance as of December 31, 2018	3,394,468	$ 0.82
Granted	875,000	1.56
Vested	(1,265,956)	0.78
Forfeited/expired	-	-
Unvested balance at December 31, 2019	3,003,512	$ 1.05

Restricted Stock Units

In connection with the closing of the Financing, there were changes to the board of directors and the Company issued initial grants to new members as well as grants to all members as compensation. In total, the Company granted 140,097 restricted stock units to the board members at a fair value of $2.07. The restricted stock units vest quarterly over twelve months. The aggregate fair value of the restricted stock units granted was $290. Restricted stock units issued to the Chairman were cancelled in January 2019.

On November 21, 2019, the Company granted 77,237 restricted stock units to certain board members at a fair value of $2.46. The restricted stock units vest quarterly over twelve months. The aggregate fair value of the restricted stock units granted was $190.

Stock-based compensation expense, which is included in general and administrative expense, for the years ended December 31, 2019, and 2018, was $1,195 and $904, respectively. As of December 31, 2019, there was $2,726 in unrecognized compensation expense, which will be recognized over a weighted average period of 1.18 years.

(In thousands, except share, per share amounts and number of lasers)

Restricted stock unit unvested are summarized in the following table:

	Number of restricted stock units	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2018	-	$ -
Granted	140,097	2.07
Vested/settled	(70,048)	2.07
Forfeited/expired	-	-
Unvested balance at December 31, 2018	70,0498	$ 2.07
Granted	77,237	2.46
Vested/settled	(60,387)	2.07
Forfeited/expired	(9,662)	2.07
Unvested balance at December 31, 2019	77,237	$ 2.46

Note 15
Income Taxes:

	Years Ended December 31,	
	2019	2018
Current:		
Federal	$ (58)	$ -
State	20	39
	(38)	39
Deferred:		
Federal	(86)	(282)
State	(25)	(21)
	(111)	(303)
Income tax benefit	$ (149)	$ (264)

The provision for income taxes includes federal, state and local income taxes currently payable and deferred taxes resulting from net operating loss carryforwards and temporary differences between the financial statement and tax bases of assets and liabilities. Valuation allowances are recorded to reduce deferred tax assets when it is not more likely than not that a tax benefit will be realized.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act made broad and complex changes to the U.S. tax code, including, but not limited to, reducing the U.S. federal corporate tax rate from 34 percent to 21 percent; eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating a new limitation on deductible interest expense; changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; and limitations on the deductibility of certain executive compensation.

(In thousands, except share, per share amounts and number of lasers)

The difference between the actual income tax benefit and that computed by applying the U.S. federal income tax rate to pretax loss from continuing operations is summarized below:

	For the Years Ended December 31,	
	2019	2018
Computed expected tax benefit	$ (827)	$ (902)
State tax (benefit)expense, net of federal effect	(106)	688
Warrant value fluctuation	-	43
Other	377	79
Net increase (decrease) in valuation allowance	407	(172)
Provision for income taxes	$ (149)	$ (264)

The computed expected tax benefit was calculated using the U.S. federal income tax rates of 21% for the years ended December 31, 2019, and 2018, respectively.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities as of December 31, 2019, and 2018 are as follows:

	December 31,	
	2019	2018
Deferred tax assets/(liabilities):		
Net operating loss carryforward	$ 43,433	$ 42,283
Intangible assets	2,046	3,340
Inventory	51	50
Reserves & accrued expenses	1,011	884
Property & equipment	389	(64)
Non-cash compensation	850	620
Goodwill	(667)	(518)
Total net deferred tax assets	47,113	46,595
Less: valuation allowance	(47,113)	(46,706)
Net deferred tax assets/(liabilities)	$ -	$ (111)

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based on the Company’s historical net losses, management does not believe that it is more-likely-than not that the Company will realize the benefits of these deferred tax assets and, accordingly, nearly a full valuation allowance has been recorded against the deferred tax assets as of December 31, 2019, and 2018. The Company’s valuation allowance against its deferred tax assets increased by $407 for the year ended December 31, 2019 and decreased by $172 for the year ended December 31, 2018.

At December 31, 2019, and 2018, the Company has federal net operating loss carryforwards of approximately $191,920 to offset future taxable income. Net operating loss carryforwards prior to 2018 begin to expire in 2020 through 2037. The Company has experienced certain ownership changes which, under the provisions of Section 382 of the Internal Revenue Code of 1986, as amended, result in annual limitations on the Company’s ability to utilize its net operating losses in the future. The February 2014, July 2014, June 2015 and May 2018 equity raises by the Company, will limit the annual use of these net operating loss carryforwards. Although the Company has not performed a Section 382 study, any limitation of its pre-change net operating loss carryforwards that would result in a reduction of its deferred tax asset would also have an equal and offsetting adjustment to the valuation allowance.

(In thousands, except share, per share amounts and number of lasers)

FASB ASC 740 “Income Taxes” contains guidance with respect to uncertain tax positions which applies to all tax positions and clarifies the recognition of tax benefits in the financial statements by providing for a two-step approach of recognition and measurement. The first step involves assessing whether the tax position is more-likely-than-not to be sustained upon examination based upon its technical merits. The second step involves measurement of the amount to recognize. Tax positions that meet the more-likely-than-not threshold are measured at the largest amount of tax benefit that is, greater than 50%, likely of being realized upon ultimate finalization with the taxing authority.

The Company does not have any uncertain income tax positions or accrued penalties and interest. If such matters were to arise, the Company would recognize interest and penalties related to income tax matters in income tax expense. The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal, state, and foreign jurisdictions, where applicable. The Company’s tax years are still under open status from 2016 to present. All open years may be examined to the extent that net operating loss carryforward are used in future periods.

Note 16
Business 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), net, is also not allocated to the operating segments.

The following tables reflect results of operations from our business segments for the periods indicated below:

Year Ended December 31, 2019

	Dermatology Recurring Procedures	Dermatology Procedures Equipment	TOTAL
Revenues	$ 23,713	$ 7,873	$ 31,586
Costs of revenues	7,033	4,283	11,316
Gross profit	16,680	3,590	20,270
Gross profit %	70.3%	45.6%	64.2%
Allocated operating expenses:			
Engineering and product development	845	157	1,002
Selling and marketing expenses	11,191	812	12,003
Unallocated operating expenses		-	10,275
	12,036	969	23,280
Income (loss) from operations	4,644	2,621	(3,010)
Interest expense, net			(515)
Loss on extinguishment of debt	-	-	(414)
Income (loss) before income taxes	$ 4,644	$ 2,621	$ (3,939)

(In thousands, except share, per share amounts and number of lasers)

Year Ended December 31, 2018

	Dermatology Recurring Procedures	Dermatology Procedures Equipment	TOTAL
Revenues	$ 21,053	$ 8,802	$ 29,855
Costs of revenues	7,378	5,357	12,735
Gross profit	13,675	3,445	17,120
Gross profit %	65.0%	39.1%	57.3%
Allocated operating expenses:			
Engineering and product development	855	210	1,065
Selling and marketing expenses	9,249	1,375	10,624
Unallocated operating expenses	-	-	8,786
	10,104	1,585	20,475
Income (loss) from operations	3,571	1,860	(3,355)
Interest expense, net	-	-	(1,142)
Other income, net	-	-	200
Income (loss) before income taxes	$ 3,571	$ 1,860	$ (4,297)

As of December 31, 2019, and 2018, total assets by reportable segment were as follows:

	December 31,	
Assets:	2019	2018
Dermatology Recurring Procedures	$ 27,620	$ 26,789
Dermatology Procedures Equipment	3,382	3,476
Other unallocated assets	16,341	17,242
Consolidated total	$ 47,343	$ 47,507

Substantially all long-lived assets were located in domestic markets for both of the years ended December 31, 2019, and 2018.

Note 17
Related Parties:

On March 30, 2018, in connection with the Financing, the Company entered into the Broadfin SPA and the Sabby SPA, each for approximately $1,000 of new investment with our then current shareholders, Broadfin and Sabby. Upon closing of the Financing, each of Sabby and Broadfin received 925,926 shares of our common stock at a price per share of $1.08. In addition, the Company also entered into a Subscription Agreement with Dr. Dolev Rafaeli, our Chief Executive Officer and Director for $1,000 to purchase 925,926 shares of our common stock at $1.08 per share. (*See Note* 1 for more information on the Financing).

During 2018, the Company had an agreement with the son of a former Board Member for direct to consumer advertising. The Company incurred $13 of expense, for the year ended December 31, 2018 and no longer uses the service.

In connection with the certain litigation, the Company has agreed to indemnify Uri Geiger and Accelmed Growth Partners, L.P. for their out of pocket costs. As of December 31, 2019, the Company has reimbursed Accelmed Growth Partners, L.P. approximately $25.

Note 18
Significant Customer Concentration:

For the year ended December 31, 2019, revenues from sales to the Company's international master distributor (GlobalMed) were $6,133, or 19.4%, of total revenues for such year. At December 31, 2019, the accounts receivable balance from GlobalMed was $661 or 15%, of total net accounts receivable. For the year ended December 31, 2018, revenues from sales to the Company's international master distributor were $6,553, or 21.9% of total revenues for such year. At December 31, 2018, the accounts receivable balance from GlobalMed was $404, or 11.9%, of total net accounts receivable. No other customer represented more than 10% of total company revenues or total accounts receivable for the years ended December 31, 2019, and 2018.

Note 19
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 the years ended December 31, 2019, and 2018, the Company's contributions to the plan were $248 and $35, respectively. On January 1, 2019, the Company elected a safe harbor match to the 401(k) defined contribution plan.

Note 20
Subsequent Events:

In March 2020, Broadfin converted the remaining 2,103 Preferred Series C Shares into 782,089 shares of common stock.

EXHIBIT 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements 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) and Form S-8 (File No.'s 333-136183, 333-161286, 333-189119, 333-208397, 333-216712 and 333-226298) of our report dated March 17, 2020, with respect to our audits of the consolidated financial statements of STRATA Skin Sciences, Inc. and Subsidiary as of December 31, 2019 and 2018 and for the years then ended, which report is included in this Annual Report on Form 10-K of STRATA Skin Sciences, Inc. for the year ended December 31, 2019.

/s/ Marcum LLP

Marcum LLP
Philadelphia, Pennsylvania
March 17, 2020

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Dolev Rafaeli, certify that:

(1) I have reviewed this annual report on Form 10-K of STRATA Skin Sciences, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 17, 2020

STRATA SKIN SCIENCES, INC.

By: /s/ Dolev Rafaeli

Dolev Rafaeli
President & Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Matthew C. Hill, certify that:

(1) I have reviewed this annual report on Form 10-K of STRATA Skin Sciences, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 17, 2020

STRATA SKIN SCIENCES, INC.

By: /s/ Matthew C. Hill
Matthew C. Hill
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), Dolev Rafaeli, the President and Chief Executive Officer of STRATA Skin Sciences, Inc. (the "Company"), and Matthew C. Hill, 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, 2019, 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 17, 2020

/s/ Dolev Rafaeli
Dolev Rafaeli
President & Chief Executive Officer

/s/ Matthew C. Hill
Matthew C. Hill
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.