

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

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, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)

13-3986004  
(I.R.S. Employer  
Identification No.)

100 Lakeside Drive, Suite 100, 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:

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, par value \$0.001 per share	Nasdaq Capital Market

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

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

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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes  No

The number of shares outstanding of our common stock as of June 30, 2015, was 8,996,686 shares. The aggregate market value of the common stock held by non-affiliates (7,379,923 shares), based on the closing market price (\$1.15) of the common stock as of June 30, 2015 was \$8,486,911.

As of March 11, 2016, the number of shares outstanding of our common stock was 10,503,393. The closing market price of our common stock as of March 11, 2016 was \$1.05.

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. 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" and similar expressions are generally intended to identify forward-looking statements, because these forward-looking statements involve risks 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 factors discussed under "Risk Factors." We undertake no obligation to update such forward-looking statements. 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 and/or competitive conditions;*
- *descriptions of plans or objectives of management for future operations, products or services;*
- *our estimates regarding the sufficiency of our cash resources, expenses, capital requirements and needs for additional financing and our ability to obtain additional financing*
- *our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;*
- *our ability to obtain and maintain regulatory approvals of our products;*
- *anticipated results of existing or future litigation; and*
- *descriptions or assumptions underlying or related to any of the above items.*

*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. 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. All subsequent forward-looking statements attributable to us or to any person acting on its 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 dedicated to developing and commercializing innovative products for the treatment and diagnosis of serious dermatological disorders. In June 2015 we completed the acquisition, or the Acquisition, of the XTRAC® Excimer Laser and the VTRAC® excimer lamp businesses from PhotoMedex, Inc. The XTRAC and VTRAC products are devices cleared by the U.S. Food and Drug Administration, or FDA, for the treatment of psoriasis, vitiligo and other skin disorders. The purchase price was \$42.5 million plus the assumption of certain business-related liabilities. These products generated \$30.6 million in revenues in 2014 and achieved year-over-year growth of 41% with a gross margin of 60.1%. We believe that these businesses acquired create a platform on which to transform STRATA into a leading medical dermatology company. We are also the developers of the

MelaFind® system, or MelaFind, a device for aiding dermatologists in the evaluation of clinically atypical pigmented skin lesions, when a dermatologist chooses to obtain additional information before making a final decision to biopsy in order to rule out melanoma. The successful commercialization of MelaFind is dependent on a number of factors, including, the establishment of reimbursement policies that include the use of MelaFind's capabilities to assist in the biopsy decision. We anticipate that it may require several years of continued effort before insurance companies establish such policies.

### **XTRAC® Systems and VTRAC Systems**

XTRAC is an ultraviolet (UV) light, excimer laser technology that emits highly concentrated UV light to treat dermatological skin disorders. It received 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, excimer lamp system that works in much the same way as the XTRAC. It received FDA clearance in August 2005 and CE mark approval in January 2006 and has been marketed exclusively in international markets.

Present in natural sunlight, 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 can clear psoriasis faster and produce longer remissions than other UVB modalities, resulting in fewer treatments to produce the desired result.

We market two XTRAC excimer models: the XTRAC Velocity is our most advanced technology which allows clinicians to treat greater surface areas of psoriatic disease in a shorter period of time than other technologies. The XTRAC Ultra Plus is also a highly effective model marketed primarily in certain international markets. Both the Velocity and the Ultra plus are capable of treating mild, moderate and severe psoriasis, vitiligo, atopic dermatitis and leukoderma.

The XTRAC 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 roughly 1,000 XTRAC lasers in use in the U.S., of which 718 systems were, as of December 31, 2015, 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 twenty-five countries. The VTRAC is marketed exclusively in international markets.

Studies have concluded that XTRAC treatment lead to significant improvement in psoriasis area and severity scores in as little 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 XTRAC 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 products have also been endorsed by the National Psoriasis Foundation, and their use for psoriasis is covered by nearly all major insurance companies, including Medicare.

XTRAC is a reimbursable procedure for psoriasis under three Current Procedural Terminology ("CPT") codes. There are three applicable CPT codes that differ based on area of treatment only. Insurance Reimbursement to physicians varies based upon insurance company and geography. 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 \$150 per treatment to \$240 per treatment.

### ***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. Generally, these drugs are administered only after both topical treatments and phototherapy have failed, or for people who have severe disease or active psoriatic arthritis.

The 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, 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 50% of insurers consider XTRAC treatments to be medically necessary for the treatment of vitiligo and therefore provide coverage.

We believe that awareness of the positive effects of XTRAC treatments is the greatest limiting factor in making XTRAC treatments available to those who suffer from psoriasis and vitiligo. Therefore, we have a direct to patient advertising campaign aimed at motivating psoriasis and vitiligo patients to seek out XTRAC treatments from our physician customers. Specific advertisements encourage prospective patients to contact the Company's patient advocacy center through telephone or web site whereby we provide information on the treatment, insurance coverage and ultimately 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.

## **The MelaFind System**

In November 2011, we received a Pre-Market Approval, or PMA, from the FDA for MelaFind, a non-invasive, point-of-care (i.e. in the doctor's office) instrument to aid in the detection of melanoma, having already received in September 2011 Conformité Européenne ("CE") Mark approval. On March 7, 2012, we installed the first commercial MelaFind System. We designed MelaFind to aid in the evaluation of clinically atypical pigmented skin lesions, when a dermatologist chooses to obtain additional information before making a final decision to biopsy in order to rule out melanoma. MelaFind acquires and displays multi-spectral (from blue to near infrared) and dermoscopic Red Green Blue ("RGB") digital data from pigmented skin lesions. It uses automatic data analysis and statistical pattern recognition to help identify lesions to be considered for biopsy to rule out melanoma. We believe that with the assistance provided by MelaFind, dermatologists may diagnose more melanomas at the most curable stages.

### ***The Melanoma Market Opportunity***

Cancer of the skin (non-melanoma and melanoma skin cancers combined) is the most common of all cancers, with over 3.5 million skin cancers in over 2 million people diagnosed annually in the U.S. It is estimated to account for almost 50% of all cancers. According to the Skin Cancer Foundation, each year there are more new cases of skin cancer than the combined incidence of cancers of the breast, prostate, lung and colon. Melanoma is responsible for approximately 75% of skin cancer mortality (death). More than 137,310 new cases of melanoma were diagnosed in the U.S. in 2014 - 63,770 non-invasive (*in situ*) and 76,100 invasive. There are three main forms of skin cancer: basal cell, accounting for approximately 75% of skin cancer cases; squamous cell, accounting for approximately 19% of skin cancer cases; and melanoma, accounting for an estimated 4% of skin cancer cases with other rare forms accounting for 2%. Melanoma places a significant burden on the healthcare system as the cost to diagnose and treat melanoma in the U.S. was estimated at \$2.36 billion (in 2010 dollars) based on a study sponsored by the National Cancer Institute.

### ***Limitations of Current Melanoma Diagnosis***

Melanoma is mainly diagnosed by dermatologists and primary care physicians using visual clinical evaluation. This subjective interpretation relies on physician experience and skill. To aid the dermatologist, MelaFind delivers an objective assessment based on numerical scores assigned to the clinically atypical skin lesion under evaluation. Furthermore, clinical examination is typically limited to the surface appearance of the clinically atypical pigmented skin lesion, and MelaFind provides information derived from up to 2.5 mm below the skin surface. Dermatologists who specialize in the management of pigmented skin lesions may also use dermoscopy, a method of viewing lesions under magnification.

### ***MelaFind Product Description***

The MelaFind system consists of a hand-held imager, which is comprised of an illuminator that shines light of 10 different specific wavelengths, including near infra-red bands; a lens system that focuses the light reflected from the lesions; and a processor employing proprietary algorithms to extract many discrete characteristics or features from the lesions.

As with many diagnostic systems, the diagnostic performance of MelaFind is characterized using two measures: (1) *sensitivity* - the ability to detect disease when it is present; and (2) *specificity* - the ability to exclude disease when it is not present. Since sensitivity and specificity are typically trade-offs, meaning that as one parameter increases the other decreases, the MelaFind lesion classifier is developed and trained with the intention of detecting melanoma with the highest possible specificity.

### ***Post-Approval Study***

In November 2011, we received written approval from the FDA for the MelaFind system PMA. In connection with the approval, we committed to conduct a Post-Approval Study ("PAS") of MelaFind. Agreement on the study protocol was reached with the FDA and the study was initiated during 2012.

In February 2014, we submitted a protocol revision request to the FDA in an attempt to clarify information with respect to the study's enrollment rate and to submit an updated enrollment plan and schedule. The protocol revisions were approved by the FDA on October 22, 2014.

On September 19, 2014, FDA responded to our PMA supplement for a change in the MelaFind output. The FDA requested that we conduct a reader study with a primary objective that would be identical to our PAS, which is to assess the lesion management decisions of dermatologists based on the MelaFind output.

Because of the overlap between the reader study and the PAS, when we submitted our 36 month progress report on the PAS on July 30, 2015, we requested that the PAS be terminated. On September 28, 2015, FDA denied our request to terminate the PAS, but stated when it reviewed the reader study data, the agency would consider the need to continue the PAS. We developed the reader study protocol in conjunction with the FDA, and the final protocol was complete on September 21, 2015. The reader study was held on October 1, 2015, and we submitted the reader study results to FDA on November 2, 2015. On December 14, 2015, the Agency informed us that it reconsidered our request to terminate the PAS and determined that we could submit our next PAS report as our final report and thus terminate the PAS early. On February 2, 2016, the FDA determined our PMA supplement on the MelaFind output was approvable.

### ***Our MelaFind Reimbursement Strategy***

The CPT Editorial Panel of the American Medical Association accepted the addition of Category III codes 0400T and 0401T to report multi-spectral digital skin lesion analysis of atypical cutaneous lesions, which applies to our MelaFind System. These codes were posted to the AMA CPT website on July 1, 2015 and were effective January 1, 2016. The codes will provide the initial basis for pursuing third party and CMS insurance coverage for MelaFind.

A favorable reimbursement environment may have a significant impact on MelaFind's adoption and commercial success. However, even if a procedure is eligible for reimbursement, the level of reimbursement may be inadequate to promote the use of the device. In addition, third-party payers may deny reimbursement if they determine that the device used in the treatment was not cost-effective or was used for a non-approved indication. While we cannot control all of the variables that may affect MelaFind's adoption and commercial use, we are developing strategies that are intended to minimize or mitigate these risks.

### **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. Currently, our XTRAC system is believed to be a competitive therapy to alternative treatments on the basis of its recognized clinical effect, cost-effectiveness and reimbursement.

In connection with the MelaFind system, a number of techniques and products for visualization and assessment of pigmented skin lesions are in use or in development. These include clinical (naked eye) examination, whole body mole mapping systems, dermoscopes (also known as "dermatoscopes"), spectrophotometric intercutaneous analysis, confocal microscopy, spectrophotometric (color) analysis and several newly identified light-based approaches. These systems rely on physician experience and expertise in recognizing patterns that are associated with melanoma and non-melanoma in order to render an interpretation and diagnosis.

### **Manufacturing**

We manufacture our XTRAC products at our 28,000 sq. ft. facility in Carlsbad, California. Our California facility is ISO 13485 certified. 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.

We are currently working to lower the cost of production of the MelaFind system by reducing labor and material costs through redesign, optimizing testing efficiencies, incorporating product improvements and utilizing where available more efficient, value-added component suppliers.

While we continue with our strategy to commercialize MelaFind we believe that we have sufficient inventory on hand to meet demand for the foreseeable future. As a result, we have terminated our contract with Askion GmbH in Germany, and plan to relocate the manufacture of the handheld components of the system to the U.S. in time to meet future demand.

### **Research and Development Efforts**

Our research and development team, including engineers, consists of approximately eleven employees. We conduct research and development activities at our facilities located in Carlsbad, California and Irvington, New York. We are in the process of closing down the Irvington operation and consolidating the work performed there in our other facilities. Currently, our research and development efforts are focused on the application of our XTRAC system to the treatment of inflammatory skin disorders. In addition, we continue to refine and improve MelaFind's hardware and software applications. Several improvements are currently in development, mostly focused on cost reductions in order to enhance the market's receptivity to the system.

### **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, 2015, 28 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, eight Australian patents and one Japanese patent relate to various aspects of MelaFind technology. We have not granted any significant licenses with respect to our intellectual property other than licenses granted in connection with our DIFOTI product on which development was discontinued in 2005.

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 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 MelaFind systems. 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, pre-market 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 FDA Act, or through a premarket approval application under Section 515 of the FDA 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 asset acquisition transaction described above.

We were required to secure premarket approval for the MelaFind system. A premarket approval application may be required for a Class II device if it is not substantially equivalent to an existing legally marketed Class I or II device (or a pre-amendments Class III device for which the FDA has yet to call for premarket approval) or if the device is a Class III premarket approval device by regulation. A premarket approval application must be supported by valid scientific evidence to demonstrate a reasonable assurance of safety and effectiveness of the device, typically including the results of clinical trials, bench tests and possibly animal studies. In addition, the submission must include, among other things, the proposed labeling. The premarket approval process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

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, labeling requirements, 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 FDA 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, VTRAC lamp and MelaFind 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 will be 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 payor. 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 payors. 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.

## ***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 has 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 payors are systematically challenging the prices charged for medical products and services. They may deny reimbursement if they determine that a prescribed device is not used in accordance with cost-effective treatment methods as determined by the payor, or is experimental, unnecessary or inappropriate. Accordingly, if less costly drugs or other treatments are available, third-party payors may not authorize, or may limit, reimbursement for the use of our products, even if our products are safer or more effective than the alternatives. 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 Centers for Medicare and Medicaid Services (CMS) under three distinct Current Procedural Terminology (CPT) codes based on the total skin surface area being treated.

As of March 11, 2016, the national rates were as follows:

- 96920 - designated for: the total area less than 250 square centimeters. CMS assigned a 2015 national payment of approximately \$157.18 per treatment;
- 96921 - designated for: the total area 250 to 500 square centimeters. CMS assigned a 2015 national payment of approximately \$172.93 per treatment; and
- 96922 - designated for: the total area over 500 square centimeters. CMS assigned a 2015 national payment of approximately \$239.89 per treatment.

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

In connection with reimbursement for MelaFind usage, the CPT Editorial Panel of the American Medical Association accepted the addition of Category III codes 0400T and 0401T to report multi-spectral digital skin lesion analysis of atypical cutaneous lesions, which applies to our MelaFind System. These codes were posted to the AMA CPT website on July 1, 2015 and were effective January 1, 2016. The codes may provide the initial basis for pursuing third party and CMS insurance coverage for MelaFind.

### **Employees**

As of March 11, 2016, we had 106 full-time employees, which consisted of two executive officers, 6 senior managers, 48 sales and marketing staff, 14 people engaged in manufacturing of lasers, 16 customer-field service personnel, 11 engaged in research and development, including seven engineers, and 9 finance and administration staff.

### **Financial Information about Geographic Areas**

See Note 17 to the consolidated financial statements included elsewhere in this filing.

## Available Information

STRATA Skin Sciences' website is [www.strataskincsciences.com](http://www.strataskincsciences.com). Our annual reports on Form 10-K, quarterly reports on 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available on our website at [www.strataskincsciences.com](http://www.strataskincsciences.com) as soon as reasonably practicable after we electronically file such reports with, or furnish them to, the Commission. The information on the Company's website is not a part of this Report.

## Item 1A. Risk Factors

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

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

Since 1999, we have primarily financed our operations through the sale of our equity securities and have devoted substantially all of our resources to research, development and commercialization of MelaFind. Our net loss for the year ended December 31, 2015 was approximately \$24.9 million, and as of December 31, 2015, we had an accumulated deficit of approximately \$207.2 million. Our profitability was further impacted by the expenses incurred in the financing of the XTRAC acquisition and will continue to be negatively impacted by interest expense related to that financing. Our losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity. Upon the closing of our acquisition of the XTRAC and VTRAC products in June 2015 we began to recognize revenues of those products, which we expect will provide sufficient cash flow to fund our current operations for the foreseeable future.

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

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

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

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

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

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

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

***Our laser treatments of psoriasis, vitiligo, atopic dermatitis and leukoderma, the MelaFind system 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. Our XTRAC systems are installed at physician offices at no upfront charge to the physician and we are paid on a per-usage method where we retain ownership of the system. We cannot assure you that our products and services will find 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 return on investment and therefore compromise our ability to increase our base of users and ensure they engage in optimal usage of our products. If, for example, such other companies have products (such as Botox or topical creams for disease management) that require less time commitment from the dermatologist and yield an attractive return on a dermatologist's time and investment, we may find that our efforts to increase our base of users are hindered.

While we have engaged in clinical studies for our psoriasis treatment and, based on these studies, we have gained FDA clearance, appropriate CPT reimbursement codes for treatment and suitable reimbursement rates for those codes, from the CMS we may face other hurdles to market acceptance. For example, practitioners in significant numbers may wait to see longer-term studies; or it may become necessary to conduct studies corroborating the role of the XTRAC system as a first-line or second-line therapy for treating psoriasis; or patients simply may not elect to undergo psoriasis treatment using the XTRAC system.

If the FDA determines that the clinical studies were not conducted in accordance with applicable FDA requirements, the FDA could take regulatory and/or legal enforcement actions against the Company and/or its products and could attempt to withdraw premarket 510(k) clearance.

Whether a treatment may be delegated and, if so, to whom and to what extent, are matters that may vary state by state, as these matters are within the province of the state medical boards. In states that may be more restrictive in such delegation, a physician may decline to adopt the XTRAC system into his or her practice, deeming it to be fraught with too many constraints and finding other outlets for the physician's time and staff time to be more remunerative. There can be no assurance that the Company 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 the Company is not successful, it 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 depends in large part on the extent to which various third parties are willing to reimburse patients or providers for the costs of medical procedures utilizing such products. These third parties include government authorities, private health insurers and other organizations, such as health maintenance organizations, whose patterns of reimbursement may change as a result of new standards for reimbursement determined by these third parties or because of the programs and policies enacted under the ACA.

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

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

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

As of March 11, 2016, we estimate, based on published coverage policies and on payment practices of private and Medicare insurance plans, that more than 90% of the insured population in the U.S. is covered by insurance coverage or payment policies that reimburse physicians for using the XTRAC system for treatment of psoriasis. We can give no assurance that health insurers will not adversely modify their reimbursement policies for the use of the XTRAC system in the future.

Our MelaFind system has not yet been approved for third party reimbursement by CMS or any private healthcare plan. Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, according to an industry report, Medicare coverage determinations for medical devices lag 15 months to five years or more behind FDA approval for that device. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state by state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the HHS. Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations. The length of time it takes for us to obtain a coverage determination may affect the ability of MelaFind to become commercially viable.

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

It is important to the success of our marketing efforts to educate physicians and technicians how to properly use our products. We rely on physicians to spend their time and money to participate in our pre-installation educational sessions. Moreover, if physicians and technicians use our products improperly, they may have unsatisfactory patient outcomes or, in the case of the XTRAC system, cause patient injury, which may give rise to negative publicity or lawsuits against us, any of which could have a material adverse effect on our reputation, revenues and 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 The Lotus Global Group, Inc., doing business as GlobalMed Technologies Co., or GlobalMed, which is the Company's master distributor over the XTRAC and VTRAC products. If we lose GlobalMed or one of these sub-distributors, our sales of phototherapy products are likely to suffer in the short term, which could have a negative effect on our revenues and 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 building and managing our sales and marketing force and marketing our products, including our ability:

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

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

***We are 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 suppliers fail to meet our needs, a change in suppliers or any significant delay in our ability to have access to such resources could have a material adverse effect on our delivery schedules, business, operating results and financial condition. Moreover, in the event we can no longer utilize this supplier or acquire this resource and must identify a new supplier or substitute a different resource, such change may trigger an obligation for us to comply with additional FDA regulatory requirements including, but not limited to, pre-marketing authorization and QSR requirements.

***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 MelaFind system is now configured on a proprietary custom-designed cart and monitor. Our ability to migrate away from such expensive customized designs to more commercially available and cheaper off-the shelf components is critical to commercial viability of the device.

***Our customers, or physicians and technicians, as the case may be, may misuse certain of our products, and product and other damages imposed on us may exceed our insurance coverage, or we may be subject to claims that are not covered by insurance.***

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

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

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

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

The success of MelaFind will depend upon the level of acceptance by dermatologists who perform skin examinations and treat patients who are at high risk for melanoma and that the evaluation information provided by MelaFind is medically useful and reliable. To date, we have achieved only a very modest penetration of the market. We believe that unless the market begins to show more enthusiasm and receptivity to the device as we migrate from the current custom cart configuration to off the shelf components, we will not be able to penetrate the market deeply enough to achieve commercial success. We will be subject to intense scrutiny before physicians will be comfortable incorporating MelaFind in their diagnostic approaches. We believe that recommendations by respected physicians will be essential for the development and successful marketing of MelaFind; however, there can be no assurance that a significant number of such recommendations will be obtained. To date, the medical community outside of our customer base has had little exposure to MelaFind. Even if we gain access to potential customers, no assurance can be given that members of the dermatological medical community will perceive a need for or accept MelaFind. This challenge is not new to the diagnostic device industry as many devices suffer the same initial market reluctance, as integrating new diagnostic tools present a challenge of adoption that many physicians are not active in overcoming. As such, physicians who are trained to trust their clinical diagnostic accuracy may not see the need to add diagnostic

tools to their already established clinical management process. Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind by the dermatological community.

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

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

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

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

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

Medical devices regulated by the FDA are subject to “general controls” which include: registration with the FDA; listing commercially distributed products with the FDA; complying with good manufacturing practices under the quality system regulations; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing. Some devices known as “510(k)-exempt” 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 the civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of Warning Letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management’s attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future.

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

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act requires us to disclose payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals at the U.S. federal level made. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business.

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

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

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

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

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

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

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

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

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

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

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

A court could order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. 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 MelaFind, 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.

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

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

- the federal healthcare programs' Anti-Kickback Law, as modified by the ACA, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services not provided as claimed and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as leading to regulations imposing certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

We and some of our third-party manufacturers and suppliers are required to comply with some or all of the FDA's drug 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 the Company 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 (10) working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect its sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require our time and capital, distract management from operating our business, and may harm our reputation and financial results.

## **Risks Relating to the XTRAC Acquisition**

***We have incurred and will incur substantial costs associated with the Acquisition and the related financing, which, being difficult to estimate, may be higher than expected and may harm the financial results of the post-Acquisition company.***

We have incurred substantial costs related to the Acquisition and the related financing. These costs include fees for attorneys, accountants, filing fees and other costs. Including the expenses incurred in December 2015 refinancing of the \$10 million in demand promissory notes issued in connection with the Acquisition, we have incurred, in aggregate, direct transaction costs of approximately \$1 million associated with the Acquisition and the related financing and additional costs associated with the consolidation and integration of operations, which cannot be fully estimated accurately at this time. We have replaced the \$10 million in demand notes with a long-term facility of \$12 million. The credit facility bears an interest rate of LIBOR plus 8.25%, which was 8.75% as of December 31, 2015.

***We may not realize the benefits we expect from the Acquisition and if the benefits of the Acquisition, if any, do not exceed the costs of integrating the businesses, our financial results may be adversely affected.***

The Acquisition is intended to provide an ongoing source of cash with which to finance our ongoing operations, to enable us to implement improvements in the MelaFind system that will make it commercially viable, and to become an attractive business platform on which to build a leading franchise in medical dermatology. We may find that the anticipated positive cash flow anticipated from the Acquisition is not sufficient to produce these results. If the financial benefits of the Acquisition, if any, do not exceed the costs of planning for and completing the Acquisition and integrating the acquired business, our financial results may be adversely affected.

***We may be subject to the risks of litigation relating to the Acquisition and the related financing.***

Any significant transaction generates some degree of litigation risk, and we may be subject to claims and actions by stockholders or other third parties who seek to disrupt the integration of the acquired business to serve their own interests. We are not currently aware of, nor do we presently anticipate, any such litigation, however if such litigation arises, the outcome of these proceedings cannot be predicted. If a plaintiff were successful in a claim against us, we could be burdened with the required payment of a material sum of money. If this were to occur, it could have an adverse effect on our financial condition and the financial condition.

We may have actions brought against us by stockholders relating to the Acquisition, the financing of the Acquisition, past transactions, changes in our stock price or other matters. Any such actions could give rise to substantial damages, and thereby have a material adverse effect on our consolidated financial position, liquidity or results of operations. Even if an action is not resolved against us, the uncertainty and expense associated with stockholder actions could harm our business, financial condition and reputation. Litigation can be costly, time-consuming and disruptive to business operations. The defense of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

***The integration of the operations of the acquired business may be difficult and may lead to adverse effects.***

While for the most part the integration of the acquired business has been successfully accomplished, there are still significant systems and procedures that require integration. The success of the Acquisition will depend, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating the acquired business. Our success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations of the acquired business. The integration of the business is a complex, costly and time-consuming process, which requires coordination of different development, regulatory, manufacturing and business teams, and involves the integration of systems, applications, policies, procedures, business processes and operations. The difficulties of combining the operations of the acquired business include, among others:

- transferring all repair and maintenance functions for the MelaFind system from the contract manufacturer in Germany and our operations in Irvington, New York to our manufacturing center in Carlsbad, California;
- training the XTRAC sales team in selling the MelaFind system;
- migration of our software and information systems, including all of the reporting and technical files for MelaFind to the computer systems acquired in the Acquisition;
- minimizing the diversion of management's attention from ongoing business concerns and facilitating the development of senior management's ability to work as a single administrative team; and
- coordinating and consolidating geographically separated businesses.

We may not accomplish this integration smoothly or successfully. If cultural conflicts and different opinions on operational matters arise, the integration could become more difficult and unpredictable. We may not succeed in addressing these risks and challenges, or any other problems encountered in connection with the Acquisition, which could have a material adverse effect our ability to realize any of the expected benefits of the Acquisition, which as a result may harm the market price of our common stock.

***Integrating the MelaFind business with the acquired business may divert management's attention away from other operations.***

Successful integration of the operations, products and personnel will require the shutdown of the Irvington, New York facility. The diversion of the attention of management from current programs to closing that facility and transferring all MelaFind R&D, operations and repair to our Carlsbad facility, the integration effort and any difficulties encountered in combining operations could prevent us from realizing the full benefits anticipated to result from the Acquisition, thus adversely affecting our business. We may incur additional costs in:

- employee redeployment, relocation or severance;
- conversion of accounting and other information systems;
- combining development, regulatory, manufacturing and commercial teams and processes;
- reorganization of facilities; and
- relocation or disposition of excess equipment.

***We have a need for operating funds and there is no guarantee that we will be able to generate those funds from the acquired business.***

Our capital and future revenue may not be sufficient to support the expenses of our operations in the near term, although based upon our current budgeting and projected cash flow models, we believe that we will be able to support our integrated operations for the foreseeable future. We plan to fund operations by the recurring revenue generated by the use of the XTRAC lasers in the U.S. plus sales of the XTRAC and VTRAC units internationally. 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 the 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.

### **Risks Relating to the 2015 Financing**

***The Debentures contain covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.***

The Debentures contain certain covenants and representations limiting our ability to incur additional indebtedness, other than specified permitted indebtedness, and from entering into or creating any liens on our assets, other than certain permitted liens. These restrictions may limit our ability to obtain additional financing, withstand downturns in our business or take advantage of business opportunities. Moreover, additional debt financing we may seek may contain terms that include more restrictive covenants, may require repayment on an accelerated schedule or may impose other obligations that limit our ability to grow our business, acquire needed assets, or take other actions we might otherwise consider appropriate or desirable.

***Our failure to avoid events of default as defined in the Debentures could require us to redeem such Debentures at a premium.***

The Debentures provide that, upon the occurrence of an “Event of Default,” the interest rate on the Debentures increases to 12%. Events of Default under the Debentures include, among other things: (1) suspension or removal from the Nasdaq Capital Market or other permissible trading market for specified time periods; (2) failure to pay principal, interest, late charges and other amounts due under the Debentures; (3) certain events of bankruptcy or insolvency of our company; and (4) failure to make payment with respect to any indebtedness in excess of \$150,000 to any third party, or the occurrence of a default or event of default under certain agreements binding our company. In addition, upon an Event of Default, the Debentures become, at the holder’s election, immediately due and payable.

Our ability to avoid such Events of Default may be affected by changes in our business condition or results of our operations, or other events beyond our control. If we were to experience an Event of Default and the holders elected to have us redeem their Debentures, we may not have sufficient resources to do so, and we may have to seek additional debt or equity financing to cover the costs of redeeming the Debentures. Any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all.

***Issuance of shares of our common stock upon the exercise of options or warrants and upon conversion of convertible debentures will dilute the ownership interest of our existing stockholders and could adversely affect the market price of our common stock.***

The exercise of outstanding stock options and warrants and conversions of outstanding convertible debentures, including the Debentures and the Warrants, and the sales of stock issuable pursuant to them would reduce a stockholder's percentage voting and ownership interest. The exercise, or potential exercise, of these options and warrants and the conversion, or potential conversion, of the debentures could adversely affect the market price of our common stock and the terms on which we could obtain additional financing. The ownership interest of our existing stockholders may be further diluted through adjustments to certain outstanding Warrants and Debentures under the terms of their anti-dilution provisions.

***We may become obligated to pay liquidated damages if we fail to file, obtain effectiveness and maintain effectiveness of a registration statement under a registration rights agreement we entered into with the Selling Stockholders.***

We have granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Debentures and the Warrants pursuant to the terms of a registration rights agreement. In addition to the registration rights, the Selling Stockholders are entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, becoming effective and maintaining an effective registration statement covering the shares underlying the Debentures and the Warrants. The liquidated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquidated damages payable is equal to 2.0% of the aggregate purchase price paid by each Purchaser, provided, however, the maximum aggregate liquidated damages payable to a Purchaser shall be 12% of the aggregate subscription amount paid by such Purchaser pursuant to the Purchase Agreement. The liquidated damages shall accrue interest at a rate of 12% per annum (or such lesser maximum amount that is permitted to be paid by applicable law), accruing on a daily basis for each event until such event is cured.

#### **Risks Relating to the December 30, 2015 Financing (the “Refinancing”)**

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

On December 30, 2015, the Company entered into a \$12.0 million credit facility pursuant to a Credit and Security Agreement (the “Agreement”) and related financing documents with MidCap Financial Trust (“MidCap”) and the lenders listed in the loan documents. We have drawn down the full \$12.0 million available to us. The Company’s obligations under the credit facility are secured by a first priority lien on all of the Company’s assets. Other financing documents included subordination agreements and other amendments with the Company’s existing debenture holders from its 2014 and 2015 financings. Our failure to abide by our on-going obligations under the loan documents could result in the lender seizing our assets.

## **Risks Relating to Our Common Stock**

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

The Sarbanes-Oxley Act of 2002 (“SOX”), as well as rules implemented by the SEC, the Public Company Accounting Oversight Board and the Nasdaq Stock Market, have required changes in the corporate governance practices of public companies. Monitoring compliance with the existing rules and implementing changes required by these rules is expensive and may increase our legal and financial compliance costs, divert management attention from operations and strategic opportunities, and make legal, accounting and administrative activities more time-consuming. Since 2008, we have retained a consultant experienced in SOX that assists us in the process of instituting changes to our internal procedures to satisfy the requirements of the SOX. We have evaluated our internal control systems in order to allow us to report on our internal controls, as required by Section 404 of the SOX. For the year ended December 31, 2014, there was a material weakness on our internal controls that was remediated as of December 31, 2015. See Item 9A included herein. As a small company with limited capital and human resources, we may need to divert management’s time and attention away from our business in order to ensure continued compliance with these regulatory requirements. We may require new information technologies systems, the auditing of our internal controls, and compliance training for our directors, officers and personnel. Such efforts may entail a significant expense. If we fail to maintain the adequacy of our internal controls as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the SOX. Any failure to maintain the adequacy of our internal controls could have an adverse effect on timely and accurate financial reporting and the trading price of our common stock.

***An active trading market for our common stock may not be sustained if our common stock is delisted from Nasdaq.***

Currently, our common stock trades on the Nasdaq Capital Market. If we fail to maintain compliance with any Nasdaq listing requirements, we could be delisted. If that were to occur, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and security analysts’ coverage of us may be reduced. Furthermore, while we believe that our common stock would trade on the OTC Bulletin Board, we would lose various advantages attendant to listing on a national securities exchange, including but not limited to, eligibility to register the sale or resale of our shares on Form S-3 and the automatic exemption from registration under state securities laws for exchange listed securities, which could have a negative effect on our ability to raise funds.

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

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

- failure of any of our products to achieve or continue to have commercial success;
- the timing of regulatory approval for our future products;
- adverse regulatory determinations with respect to our existing products;
- results of our research and development efforts and our clinical trials;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the U.S. and foreign countries;
- our ability to manufacture our products to commercial standards;

- developments concerning our clinical collaborators, suppliers or marketing partners;
- changes in financial estimates or recommendations by securities analysts;
- public concern over our products;
- developments or disputes concerning patents or other intellectual property rights;
- product liability claims and litigation against us or our competitors;
- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of third-party reimbursement in the U.S. and other countries;
- changes in accounting principles or practices;
- general economic, industry and market conditions; and
- future sales of our common stock.

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

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

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

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

In addition, Section 203 of the Delaware General Corporation Law generally limits our ability to engage in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock.

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**

There are no unresolved comments from the staff of the Securities and Exchange Commission.

**Item 2. Properties**

We lease a 10,672 sq. ft. facility in Horsham, Pennsylvania that houses our executive offices and marketing. The term of the lease runs through November 30, 2016. We also lease 21,700 sq. ft. of office, laboratory and assembly space in a building in Irvington, New York. The lease expires in December 2016 and will not be renewed.

We lease 28,000 sq. ft. facility consisting of office, manufacturing and warehousing space in Carlsbad, California. The lease expires on September 30, 2017. 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 and our subsidiary 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.

**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 11, 2016, we had 10,503,393 shares of common stock issued and outstanding. This did not include (i) options to purchase 2,684,352 shares of common stock, of which 1,729,677 were vested as of March 11, 2016, (ii) warrants to purchase up to 16,828,419 shares of common stock, all of which warrants were vested or (iii) convertible debentures convertible into 46,415,126 shares of common stock.

Our common stock is listed on the Nasdaq Global Select Market ("Nasdaq") under the symbol "SSKN." The following table sets forth, for the periods indicated, the high and low closing sale prices per share of our common stock:

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2015:		
Fourth Quarter	\$1.21	\$1.07
Third Quarter	1.25	1.05
Second Quarter	2.48	1.15
First Quarter	3.57	1.17
Year Ended December 31, 2014:		
Fourth Quarter	\$2.30	\$1.11
Third Quarter	3.50	1.65
Second Quarter	6.30	3.10
First Quarter	8.90	6.10

On March 11, 2016, the last reported sale price for our common stock on Nasdaq was \$1.05 per share. As of March 11, 2016, we had approximately 73 stockholders of record, without giving effect to determining the number of stockholders who held shares in "street name" or other nominee accounts.

#### 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.

#### 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, 2015. See Notes 1 and 15 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	2,684,352	\$1.54	10,565,648
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>2,684,352</b>	<b>\$1.54</b>	<b>10,565,648</b>

#### 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 financial data, in this narrative, are expressed in thousands, except for the earnings per share. The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and related notes included elsewhere in this Report. Amounts are reported in thousands.*

#### Introduction, Outlook and Overview of Business Operations

STRATA Skin Sciences, Inc. ("STRATA" or "we" or the "Company") (formally MELA Sciences, Inc.) is a medical technology company dedicated to developing and commercializing innovative products for the diagnosis and treatment of serious dermatological disorders. In June 2015 we completed the acquisition of the XTRAC System and the VTRAC System businesses from PhotoMedex, Inc. The XTRAC and VTRAC products are FDA cleared devices for the treatment of psoriasis, vitiligo and other skin disorders. The purchase price was \$42,528 plus the assumption of certain business-related liabilities. These products generated \$30,600 in revenues in 2014 and achieved year-over-year growth of 41% with a gross margin of 60.1%, with the prior company on a pro forma basis. Management believes that these businesses acquired create a platform on which to transform STRATA into a leading medical dermatology company. Management further believes that the cash flow generated by these businesses will be sufficient to finance our operations for the foreseeable future.

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 308nm ultraviolet light to affected areas of skin, leading to psoriasis clearing and vitiligo repigmentation, following a series of treatments. As of December 31, 2015, there were 718 XTRAC systems placed in dermatologists' offices in the United States under our recurring revenue model, up from 620 at the end of December 2014. Under the recurring revenue model, the XTRAC system is placed in a physician's office and revenue is recognized on a per procedure basis. The XTRAC system's use for psoriasis is covered by nearly all major insurance companies, including Medicare. The VTRAC Excimer Lamp system, offered internationally, 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 2015, over 354,000 XTRAC laser treatments were performed on approximately 22,000 patients in the United States.

The financial results of the XTRAC and VTRAC businesses have been included in the results of operations subsequent to June 22, 2015, the date of the acquisition. The assets of the acquired businesses and liabilities assumed have been consolidated as of June 22, 2015.

MelaFind is a non-invasive, point-of-care (i.e., in the doctor's office) instrument designed to aid in the dermatologists' decision to biopsy pigmented skin lesions, particularly melanoma. The successful commercialization of MelaFind is dependent on many factors, one of which is the establishment of reimbursement policies that include the use of the MelaFind's capabilities to assist in the biopsy decision. Management anticipates that it may require several years of continued effort for insurance companies to establish such policies.

In July 2015, the CPT® Editorial Panel of the American Medical Association posted to the AMA's website the list of Category III codes that became effective January 16, 2016. These codes included T0400 and T0401, which apply to our MelaFind system. This action followed from our application submitted in July 2014 for a Current Procedural Terminology ("CPT") code, which is necessary for Medicare Part B reimbursement by the Centers for Medicare and Medicaid Services ("CMS").

## **Key Technology**

- *XTRAC® Excimer Laser.* XTRAC received FDA clearance in 2000 and has since become a widely recognized treatment among dermatologists for psoriasis and other skin diseases. The XTRAC System delivers ultra-narrowband ultraviolet B ("UVB") light to affected areas of skin. Following a series of treatments typically performed twice weekly, psoriasis remission can be achieved and vitiligo patches can be re-pigmented. XTRAC is endorsed by the National Psoriasis Foundation, and its use for psoriasis is covered by nearly all major insurance companies, including Medicare. We estimate that more than half of all major insurance companies now offer reimbursement for vitiligo as well, a figure that is increasing.
- *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.
- *MelaFind®.* MelaFind received a Pre-Market Approval, or PMA, from the FDA, in November 2011, having already received in September 2011 Conformité Européenne ("CE") Mark approval. MelaFind is a non-invasive, point-of-care, (i.e. in the doctor's office) instrument to aid dermatologists in their decision to biopsy suspicious pigmented lesions, (e.g. melanoma). MelaFind aids in the evaluation of clinically atypical pigmented skin lesions, when a dermatologist chooses to obtain additional information before making a final decision to biopsy in order to rule out melanoma. MelaFind acquires and displays multi-spectral (from blue to near infrared) images and dermoscopic Red Green Blue ("RGB") digital data from pigmented skin lesions.

## Sales and Marketing

As of December 31, 2015, our sales and marketing personnel consisted of 49 full-time employees, inclusive of 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. 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, inventories, impairment of property and equipment and of intangibles 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. These critical accounting policies and the significant estimates made in accordance with these policies have been discussed with our Audit Committee.

**Revenue Recognition.** We recognize revenues from product sales when the following four criteria have been met: (i) the product has been delivered and we have no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of provisions for expected returns and cash discounts.

We ship most of our products FOB shipping point, although from time to time certain customers, for example governmental customers, will be granted FOB destination terms. Among the factors we take into account when determining the proper time at which to recognize revenue are (i) when title to the goods transfers and (ii) when the risk of loss transfers. Shipments to distributors or physicians that do not fully satisfy the collection criteria are recognized when invoiced amounts are fully paid or fully assured and included in deferred revenues until that time.

For revenue arrangements with multiple deliverables within a single, contractually binding arrangement (usually sales of products with separately priced extended warranty), each element of the contract is accounted for as a separate unit of accounting when it provides the customer value on a stand-alone basis and there is objective evidence of the fair value of the related unit.

We have two distribution channels for our phototherapy treatment equipment. We either (i) 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) sell our lasers through a distributor or directly to a physician. In some cases, when the laser is placed in a physician's office at no charge, we and the customer stipulate to a quarterly or other periodic target of procedures to be performed, and accordingly revenue is recognized ratably over the period.

When we place a laser in a physician's office, we generally recognize revenue based on the number of patient treatments performed, or purchased under a periodic commitment, by the physician. Amounts collected with respect to treatments to be performed through laser-access codes that are sold to physicians free of a periodic commitment, but not yet used, are deferred and recognized as a liability until the physician performs the treatment. Unused treatments remain our obligation because the treatments can only be performed on our-owned equipment. Once the treatments are performed, this obligation has been satisfied.

We defer substantially all revenue from sales of treatment codes ordered by and performed by our customers within the last two weeks of the period in determining the amount of procedures performed by our customers. Management believes this approach closely approximates the actual amount of unused treatments that exist at the end of a period.

For our MelaFind products, we utilize a direct sales force which sells the system to the physician's office and we recognize revenue upon shipment of the system to the purchaser after receipt of the fully-executed purchase agreement.

**Inventory.** We account for inventory at the lower of cost or market. Cost is determined to be purchased cost for raw materials and the production cost (materials, 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 therefore is disclosed in conjunction with 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 have been met, and until that time, the unit is carried on our books as inventory. Revenue is not recognized from these distributors until payment is either assured or paid in full.

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, 2015 and 2014, allowance for doubtful accounts was \$45 and \$95, respectively.

**Property and Equipment.** As of December 31, 2015 and 2014, we had net property and equipment of \$13,851 and \$1,961, respectively. For the year ended December 31, 2015, the most significant component relates to the XTRAC lasers placed by us in physicians' offices. We own the equipment and charge the physician on a per-treatment basis for use of the equipment. The recoverability of the net carrying value of the lasers is predicated on continuing revenues from the physicians' use of the lasers. 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, automobiles 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 and Intangibles Assets.** Our balance sheet includes goodwill and other intangible assets which affect the amount of future period amortization expense and possible impairment expense that we will incur. 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, 2015 and 2014, we had \$24,155 and \$37 of goodwill and other intangibles, accounting for 47.0% and 0.2% of our total assets, respectively. The goodwill is not amortizable; the other intangibles are. The determination of the value of such intangible assets requires management to make estimates and assumptions that affect our consolidated financial statements. We test our goodwill for impairment at least annually. The acquisition of the XTRAC and VTRAC businesses that gave rise to the recorded goodwill closed on June 22, 2015. Management performed a qualitative assessment and concluded that there were no indicators of impairment as of December 31, 2015. This test will be 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.

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.

**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 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 our deferred tax assets and liabilities and any valuation allowance recorded against our net 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. The Company does not have any unrecognized tax benefits 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.

**Stock-based compensation.** We account for stock based compensation to employees in accordance with “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 portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in our consolidated statement of operations.

The fair value of employee stock options is estimated using a Black-Scholes valuation model. Compensation costs are recorded using the graded vesting attribution method over the vesting period, net of estimated forfeitures. The total share-based compensation expense was \$1,753 and \$413 for the years ended December 31, 2015 and 2014, 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. Our derivative financial instruments are considered to be significant unobservable inputs (level 3).

**Results of Operations** (The following financial data, in this narrative, are expressed in thousands, except for the earnings per share.)

## Revenues

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

	For the Year Ended December 31,	
	<u>2015</u>	<u>2014</u>
Dermatology Recurring Procedures	\$ 14,616	\$ -
Dermatology Procedures Equipment	3,591	-
Dermatology Imaging	<u>288</u>	<u>915</u>
Total Revenues	<u>\$ 18,495</u>	<u>\$ 915</u>

We completed the asset purchase of the XTRAC and VTRAC businesses on June 22, 2015 and as such, these revenues are included only for the period of June 23, 2015 through December 31, 2015. Therefore, there are no corresponding revenues for the year ended December 31, 2014.

### Dermatology Recurring Procedures

Recognized treatment revenue for the year ended December 31, 2015 was \$14,616 which approximates 194,000 treatments, with prices 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 have a direct to patient program for XTRAC advertising in the United States targeted at 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 continue to increase our advertising expenditures in this area to reach the more than 10 million patients in the United States afflicted with these diseases.

We defer substantially all sales of treatment codes ordered by and delivered to the customer within the last two weeks of the period in determining the amount of procedures performed by our physician-customers. Management believes this approach closely approximates the actual amount of unused treatments that existed at the end of a period. As of December 31, 2015, we deferred net revenues of \$20 under this approach.

### Dermatology Procedures Equipment

For the year ended December 31, 2015 dermatology equipment revenues were \$3,591. Internationally, we sold 52 systems for the year ended December 31, 2015, 31 of which were VTRAC systems.

### Dermatology Imaging

For the year ended December 31, 2015 and 2014, imaging revenues were \$288 and \$915, respectively. Imaging revenues are generated from the MelaFind systems, through direct capital equipment sales and through a leasing model. Under the leasing model, there is an upfront installation fee and a monthly usage fee based on the number of lesions examined.

### **Cost of Revenues**

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

	For the Year Ended December 31,	
	<u>2015</u>	<u>2014</u>
Dermatology Recurring Procedures	\$ 4,680	\$ -
Dermatology Procedures Equipment	1,989	-
Dermatology Imaging	<u>7,050</u>	<u>4,935</u>
Total Cost of Revenues	<u>\$13,719</u>	<u>\$4,935</u>

As we completed the asset purchase of XTRAC and VTRAC businesses on June 22, 2015, cost of revenues related to this business was included from June 23, 2015 through December 31, 2015. There were no corresponding cost of revenues for the year ended December 31, 2014.

Cost of revenues have increased to \$13,719 for the year ended December 31, 2015 compared to \$4,935 for the year ended December 31, 2014. During the year ended December 31, 2015 we initiated plans to develop an updated version of the MelaFind system and, accordingly, determined that a majority of our existing inventory of MelaFind systems and related parts exceeded our requirements. As a result, we wrote-off the excess and obsolete inventory on our MelaFind systems and related components and incurred a charge of \$4,818. We also had an impairment charge of \$920 of property and equipment related to the MelaFind systems.

### **Gross Profit Analysis**

Gross profit increased to \$4,776 for the year ended December 31, 2015 from (\$4,020) during the same period in 2014. As a percentage of revenues, the gross margin was 25.8% for the year ended December 31, 2015 from (439.3%) during the same period in 2014.

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

	For the Year Ended December 31, 2015				For the Year Ended December 31, 2014
	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Dermatology Imaging	Total	
Revenues	\$ 14,616	\$ 3,591	\$ 288	\$ 18,495	\$ 915
Cost of revenues	<u>4,680</u>	<u>1,989</u>	<u>7,050</u>	<u>13,719</u>	<u>4,935</u>
Gross profit	<u>\$ 9,936</u>	<u>\$ 1,602</u>	<u>(\$ 6,762)</u>	<u>\$ 4,776</u>	<u>(\$ 4,020)</u>
Gross margin percentage	68.0%	44.6%	(2,347.8%)	25.8%	(439.3%)

The primary reason for the changes in gross profit for the year ended December 31, 2015, compared to the same period in 2014, was the acquisition of the XTRAC and VTRAC businesses on June 22, 2015. The gross profit related to these businesses was included from June 23, 2015 through December 31, 2015 and was allocated to the two Dermatology Procedures segments. There was no corresponding gross profit for the year ended December 31, 2014. Additionally, during the year ended December 31, 2015 we initiated plans to develop an updated version of the MelaFind system and, accordingly, determined that a majority of our existing inventory of MelaFind systems and related parts exceeded our requirements. As a result, we wrote-off the excess and obsolete inventory on our MelaFind systems and related components and incurred a charge of \$4,818. We also had an impairment charge of \$920 of property and equipment related to the MelaFind systems.

### ***Engineering and Product Development***

Engineering and product development expenses for the year ended December 31, 2015 increased to \$2,029 from \$1,641 for the year ended December 31, 2014. The increase related to \$780 in engineering and product development expenses related to the XTRAC and VTRAC businesses for the year ended December 31, 2015. As the XTRAC and VTRAC acquisition was completed on June 22, 2015, the expenses were included only from June 23, 2015 through December 31, 2015. There was no corresponding expense for the year ended December 31, 2014. Offsetting some of the increase was planned cost reductions around the MelaFind division. Ongoing research and development efforts for the MelaFind technology is focused on future product enhancements.

### ***Selling and Marketing Expenses***

For the year ended December 31, 2015, selling and marketing expenses increased to \$9,194 from \$3,140 for the year ended December 31, 2014. The increases were related to the XTRAC and VTRAC businesses of \$7,322. As the XTRAC and VTRAC acquisition was completed on June 22, 2015, the expenses were included only from June 23, 2015 through December 31, 2015. There was no corresponding expense for the year ended December 31, 2014. Offsetting some of the increases, were decreases in the MelaFind Division primarily related to salary and headcount decreases and overall impact of cost reduction initiatives.

### ***General and Administrative Expenses***

For the year ended December 31, 2015, general and administrative expenses increased to \$10,028 from \$7,821 for the year ended December 31, 2014. The changes were due to the following reasons:

- In the year ended December 31, 2015, we recorded \$827 in stock-based compensation expense related to the special option issuance to certain board directors.
- In the year ended December 31, 2015, we had additional expenses of \$1,955 in general and administrative expenses related the XTRAC and VTRAC businesses. As the XTRAC and VTRAC acquisition was completed on June 22, 2015, the expenses were included only from June 23, 2015 through December 31, 2015. There was no corresponding expense for the year ended December 31, 2014.
- In the year ended December 31, 2015, we recorded \$456 in acquisition costs related to the asset purchase.
- Offsetting some of the increases, were decreases in the MelaFind Division primarily related to salary and headcount decreases and overall impact of cost reduction initiatives.

### ***Interest Expense, Net***

Interest expense for the year ended December 31, 2015 was \$10,200 compared to \$2,372 in the year ended December 31, 2014. Interest expense during the periods of 2015 and 2014 relate to the 4% senior convertible debentures issued in July 2014, which included amortization of the related debt discount and deferred financing fees. The 2015 period also included interest expense related to both the senior note and the 2.25% senior convertible debentures issued on June 22, 2015. Additionally, approximately \$3,601 of interest expense was recognized as a result of the conversion of \$4,815 of debentures into common stock during the year ended December 31, 2015.

### ***Change in Fair Value of Warrant Liability***

In accordance with FASB ASC 470, “*Debt – Debt with Conversion and Other Options*” (“ASC Topic 470”) and FASB ASC 820, *Fair Value Measurements and Disclosures* (“ASC Topic 820”), we measured the fair value of our warrants that were recorded at their fair value and recognized as liabilities as of December 31, 2015, and recorded \$1,814 in other income for the year ended December 31, 2015. We measured the fair value of these warrants as of December 31, 2014, and recorded \$8,103 in other income for the year ended December 31, 2014.

### ***Registration Rights Liquidated Damages***

In connection with the February 2014 financing, we granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Series A Preferred Stock and the warrants pursuant to the terms of a Registration Rights Agreement. In addition to the registration rights, the Purchasers were entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, effectiveness and maintaining an effective registration statement covering the shares underlying the Series A Preferred Stock and the warrants. We were unable to meet certain filing and effectiveness requirements and as a result paid liquidated damages to the Purchasers in the aggregate amount of \$3,420 for the year ended December 31, 2014.

### ***Other Income (Expense), net***

Other income, net for the year ended December 31, 2015 was \$33 compared to \$150, for the year ended December 31, 2014. Other income mainly represents royalty income we earn each quarter from Kavod Dental GmbH on the licensing of certain technology patents.

### ***Income Taxes***

Income tax expense for the year ended December 31, 2015 was \$119 compared to \$0 for the year ended December 31, 2014. The expense is comprised of the change in deferred tax liability related to goodwill. Goodwill is an amortizing asset according to tax regulations. This generates a deferred tax liability that is not used to offset deferred tax assets for valuation allowance considerations.

### ***Net Loss***

The factors described above resulted in net loss of \$24,947 during the year ended December 31, 2015, as compared to a net loss of \$14,145 during the year ended December 31, 2014.

### ***Deemed Dividend***

As approved by the stockholders on September 30, 2015, we modified the terms of warrants, held by the investors that participated in the June 2015 Debentures in excess of \$5 million, which included reducing the exercise price of such warrants to \$0.75 and adding down-round price protection provisions. These warrants had previously been classified and recorded in stockholders' equity. As a result of the modification these warrants now meet the definition of a derivative. As a result of the modification, we recorded a deemed dividend related to these warrants of \$2,962, which was determined as the difference between the fair value of these warrants immediately before the modification and immediately after. The binomial method was used to value the warrants.

For the year ended December 31, 2014, we recorded a deemed dividend related to beneficial conversion feature on convertible preferred stock of \$1,887.

### ***Non-GAAP adjusted income (loss)***

As a result of our acquisition of the XTRAC and VTRAC products, we have determined to supplement our condensed consolidated financial statements, prepared in accordance with GAAP, presented elsewhere within this report, we will provide certain non-GAAP measures of financial performance. These non-GAAP measures include non-GAAP adjusted income.

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, 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.

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,		
	2015	2014	Change
Net loss	(\$ 24,947)	(\$ 14,145)	(\$10,802)
Adjustments:			
Income taxes	119	-	119
Depreciation and amortization	4,051	1,790	2,261
Interest expense, net	1,329	242	1,087
Non-cash interest expense	8,871	2,130	6,741
EBITDA	(10,577)	(9,983)	(594)
Stock-based compensation expense	1,753	413	1,340
Acquisition costs	456	-	456
Change in fair value of warrants	(1,814)	(8,103)	6,289
Registration rights liquidated damages	-	3,420	(3,420)
Impairment of MelaFind property and equipment	920	-	920
MelaFind Inventory write off	4,818	1,084	3,734
Non-GAAP adjusted EBITDA	(\$ 4,444)	(\$ 13,169)	\$ 8,725

### *Liquidity and Capital Resources*

As of December 31, 2015 we had \$4,900 of working capital compared to \$15,016 as of December 31, 2014. Cash and cash equivalents were \$3,318, including restricted cash of \$15, as of December 31, 2015, as compared to \$11,434 as of December 31, 2014.

In February 2014, we sold to investors for net proceeds of \$11,400 an aggregate of 12,300 shares of Series A convertible preferred stock, convertible into 1.5 million shares of common stock at a conversion price of \$8.40, and warrants to purchase up to 1.3 million shares of the our common stock. In addition, as a condition of the financing, our directors purchased an aggregate of 20,271 shares of common stock, at a price of \$7.40 per share, for aggregate gross proceeds of \$150.

In July 2014, we raised additional net proceeds of approximately \$13,800 through the issuance of 4% senior secured convertible debentures due July 2019, Series B convertible preferred stock and warrants to purchase common stock. The debentures are convertible at any time into an aggregate of approximately 5.8 million shares of our common stock at a price of \$2.565 per share. Our obligations under the debentures are secured by a first priority lien on all of our intellectual property. During 2015, \$4,593 of debentures and \$5,282 of preferred stock were converted into common stock. Additionally, we repurchased \$103.

In June 2015, we raised additional gross proceeds of approximately \$42,500 through the issuance of \$32,500 of 2.25% senior secured convertible debentures due June 2020, \$10,000 of Senior secured notes and warrants to purchase common stock. The debentures are convertible at any time into an aggregate of approximately 43.3 million shares of our common stock at a price of \$0.75 per share. Our obligations under the debentures are secured by a subordinated first priority lien on all of our assets. During 2015, \$222 of debentures were converted into common stock.

On December 30, 2015, the Company entered into a \$12,000 credit facility pursuant to a Credit and Security Agreement (the "Agreement") and related financing documents with MidCap Financial Trust ("MidCap") and the lenders listed therein. Under the 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 proceeds of this first tranche were used to repay \$10,000 principal amount of short-term senior secured promissory notes, plus associated interest, loan fees and expenses. The second tranche was drawn for \$1,500 on January 29, 2016. The Company's obligations under the credit facility are secured by a first priority lien on all of the Company's assets. Other financing documents included subordination agreements and other amendments with the Company's existing debenture holders from its 2014 and 2015 financings.

We have experienced recurring losses and negative cash flow from operations since inception. 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. The XTRAC and VTRAC businesses, which were acquired on June 22, 2015, have had positive cash flows from operations prior to the acquisition. We believe that our cash as of December 31, 2015 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 first quarter of 2017.

Net cash and cash equivalents used in operating activities was \$6,585 for the year ended December 31, 2015 compared to cash used in operating activities of \$17,709 for the year ended December 31, 2014. The primary reasons for the change was the cash from operations generated by the XTRAC and VTRAC business, which was acquired on June 22, 2015, and a continued effort to reduce expenses.

Net cash and cash equivalents used in investing activities was \$44,224 for the year December 31, 2015 compared to cash provided by investing activities of \$17 for the year ended December 31, 2014. The primary reason for the change was the asset purchase of the XTRAC and VTRAC business during year ended December 31, 2015.

Net cash and cash equivalents provided by financing activities was \$42,670 for the year ended December 31, 2015 compared to cash provided by financing activities of \$25,343 for the year ended December 31, 2014. In the year ended December 31, 2015, we completed a financing consisting of Senior secured notes amounting to \$10,000 and senior secured convertible debentures of \$32,500; repaid the Senior secured notes of \$10,000 and drew down \$10,500 on a long-term debt facility. In the year ended December 31, 2014, we received proceeds from the private placement/public offerings of \$11,458 and \$15,000 from convertible preferred stock and debentures.

### **Off-Balance Sheet Arrangements**

At December 31, 2015, 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.

### **Item 7A. Quantitative and Qualitative Disclosure about Market Risk**

Our exposure to market risk is confined to our cash, cash equivalents, and short-term investments. We invest in high-quality financial instruments, primarily money market funds, with the average effective duration of the portfolio within one year which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments. We are exposed to credit risks in the event of default by the financial institutions or issuers of investments in excess of FDIC insured limits. We perform periodic evaluations of the relative credit standing of these financial institutions and limit the amount of credit exposure with any institution.

**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**

*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, 2015. Based on that evaluation, management has concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level 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 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 the Company’s 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 the Company’s internal control over financial reporting was effective as of December 31, 2015.

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 the Company’s disclosure controls and procedures or its internal control over financial reporting will prevent or detect all errors and all fraud.

The design of any system of controls is based in part on 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. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

### ***Remediation of Material Weaknesses in Internal Control Over Financial Reporting***

In Item 9A of the Company's Annual Report on Form 10K for the fiscal year ended December 31, 2014, management reported a material weakness in its internal control over financial reporting.

Specifically, the material weakness related around the fact that in early 2014, we changed our MelaFind business model from solely a leased-based model to include a capital sales option and, accordingly, at December 31, 2013, we reclassified a portion of our MelaFind parts, components and systems from fixed assets to inventory. In connection with the audit of our financial statements for the year ended December 31, 2014, Management noted that the two accounts impacted by the changes in our business model, inventory and fixed assets, took longer than anticipated to reconcile.

Further, an unusually large number of transactions involving fixed assets and inventory occurred at the end of December 2014 due primarily to the Company's increased sales and lease return activities which needed further accounting review and analysis. As a result of these factors, the closing process was delayed and there were a number of post-closing adjustments in these and other areas. Management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by COSO in *2013 Internal Control-Integrated Framework* and concluded that our internal controls specifically related to proper review and monitoring were not operating effectively at December 31, 2014.

Management implemented certain remediation procedures during 2015 that had been developed and adopted following the filing of our 2014 Annual Report on Form 10-K, which were intended to reasonably assure Management that our disclosure controls and procedures and internal controls over financial reporting are effective. During the third quarter of 2015, we moved our financial closing and reporting processes, and the related system of internal control over financial reporting to the new finance organization. This organization was acquired as part of the asset purchase on June 22, 2015, including the Chief Financial Officer, which provided the Company an enhanced finance organization in quality and quantity over the prior organization. Additionally, this finance organization had maintained an effective control environment, prior to the acquisition, for several years.

### ***Changes in Internal Control over Financial Reporting***

Other than the control improvements discussed above, there have 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 eight meetings.

The following sets forth certain biographical information concerning our current directors and our executive officers as of March 11, 2016.

<u>Name</u>	<u>Position</u>	<u>Age</u>
Jeffrey F. O'Donnell, Sr.	Chairman of the Board	55
Michael R. Stewart	President, Chief Executive Officer and Director	58
R. Rox Anderson	Director (September 30, 2015)	64
Samuel E. Navarro	Director	59
David K. Stone	Director	59
Kathryn Swintek	Director	63
LuAnn Via	Director	62

**Jeffrey F. O'Donnell, Sr.** was appointed to serve on our Board of Directors in January 2014 and appointed as Chairman of the Board of Directors in March 2014. Mr. O'Donnell is currently President and Chief Executive Officer of Trice Medical, an emerging growth medical device company developing optical needles used by orthopedic surgeons to diagnose soft tissue damage of joints. In 2008, Mr. O'Donnell started Embrella Cardiovascular, Inc., a medical device startup company. In July 2009, Mr. O'Donnell was named President and Chief Executive Officer of the company, which was later sold to Edwards Lifesciences Corporation in March 2011. From 1999 through 2009, Mr. O'Donnell served as President, Chief Executive Officer and a Director of PhotoMedex, Inc., a public medical device company listed on the Nasdaq Stock Market. From 1995 through 2000, Mr. O'Donnell was at Cardiovascular Dynamics, Inc., a company focused in interventional cardiology, where he served in a number of senior executive positions, including President and Chief Operating Officer and Chairman and Chief Executive Officer. Cardiovascular Dynamics became Radiancance Medical Systems, which was purchased by Endologix, Inc. in 2000. Mr. O'Donnell remained on the Board of Directors until 2012. Currently, Mr. O'Donnell sits on the Board of Directors of BioSig Technologies. We believe Mr. O'Donnell's qualifications to serve on our Board of Directors include his extensive experience in the healthcare industry; his traditional corporate background with emerging growth company experience; and his past experience as a president, chief executive officer or director of several other companies.

**Michael R. Stewart** became the Company's President and Chief Executive Officer on December 15, 2014 and has been a member of the Company's Board of Directors since August 5, 2014. Mr. Stewart had most recently been Executive Vice President and Chief Operating Officer of PhotoMedex, a NASDAQ-traded global medical device and skin health company. Mr. Stewart previously served as president, chief executive officer and board member of Surgical Laser Technologies, Inc. from 1999 until its sale in 2002 to PhotoMedex. Post-acquisition and during his continuing tenure with PhotoMedex, Mr. Stewart led the domestic and international sales organizations, marketing, product development and engineering, manufacturing and service operations. He successfully developed and executed a reimbursement strategy for the company's flagship dermatology product that resulted in the issuance of new CPT codes and reimbursement by the CMS and coverage policies with virtually all major insurance companies. We believe Mr. Stewart's qualifications to serve on the Board of Directors include his extensive experience in the healthcare industry, his corporate background and his past experience as a senior executive and chief executive officer of public companies in our industry.

**R. Rox Anderson** has served as a member of our Board of Directors since September 30, 2015. Dr. Anderson is a professor at Harvard Medical School, an adjunct professor at MIT, and director of the Wellman Center for Photomedicine at Massachusetts General Hospital in Boston. Wellman is the world's largest academic facility dedicated to photomedicine. After graduating from MIT, Dr. Anderson received his M.D. degree magna cum laude from a joint MIT-Harvard medical program, Health Sciences and Technology. He conceived and developed non-scarring dermatologic surgery using selectively-absorbed laser pulses, which is now the preferred basis for treatment of birthmarks, pigmented lesions, tattoos, hypertrichosis and other conditions. He has made many contributions to the understanding and development of laser-tissue interactions, tissue optics, photodynamic therapy, and optical diagnostics. Dr. Anderson also practices dermatology, teaches at Harvard and MIT, and conducts research at the Wellman Center for Photomedicine. Active research includes diagnostic tissue imaging and spectroscopy, photodynamic therapy, mechanisms of laser-tissue interactions, adipose tissue biology, low-level light effects and novel therapies for skin disorders. Dr. Anderson received the Presidential Citation, the Ellet H. Drake and William Mark awards from the American Society for Laser Medicine & Surgery, Inc., serves on the editorial board of such society's journal and was its 2009 president. Dr. Anderson currently serves the American Society for Laser Medicine & Surgery, Inc. as director of government communications and education. This is the first year Dr. Anderson has been nominated to the Board of Directors. We believe Dr. Anderson's qualifications to serve on our Board of Directors include his extensive experience in the healthcare industry, including his strong dermatological research and analysis background.

**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, 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.

**David K. Stone** has served as a member of our Board of Directors since December 2011 and served as Chairman of our Board of Directors from June 2013 to November 2013. In 2006, Mr. Stone founded Liberty Tree Advisors, LLC, a life sciences investment banking and consulting firm where he is currently a Managing Director. Prior to this, from 2000 to 2006 Mr. Stone was a Managing Director and Partner at Flagship Ventures, a venture capital fund focused in the life sciences industry. From 1989 to 1999, Mr. Stone led the biotechnology equity research team at Cowen & Company. Mr. Stone is currently on the Board of Directors of PAKA Pulmonary Pharmaceuticals. He has also served on the Board of Directors of Seahorse Bioscience, where he was Chairman of the Audit Committee from 2001 to November 2015 when Seahorse Bioscience was acquired by Agilent. He served on the Board of Directors of Oscient Pharmaceuticals, where he served as Chairman from 2005 to 2009. We believe Mr. Stone's qualifications to serve on our Board of Directors include his extensive experience as a biopharmaceutical industry research analyst and his venture capital work with numerous pharmaceutical and medical device companies.

**Kathryn Swintek** was elected to our Board of Directors, in April 2013. Since August 2010, Ms. Swintek has been a Managing Partner and member of the Investment Committee of Golden Seeds Fund 2, and Managing Director of Golden Seeds LLC, an angel investment forum backing women owned or managed early stage and growth companies. Prior to Golden Seeds, Ms. Swintek was a senior executive at BNP Paribas from November 1989 to April 2008, where she most recently served as Managing Director and Global Co-Head of its London-based Financial Sponsors Coverage Group. From 1974 to 1989, Ms. Swintek was a senior executive with Irving Trust Company (now known as BNY Mellon), where she was a Sr. Vice President and held positions in risk management, and acquisition finance, and managed business relationships for the International Division in North Africa and the Near East, as well as in France, where she served as Representative while residing in Paris. Ms. Swintek is a former Chair of the Governing Board and the Executive Committee of C200, a business women's leadership organization, which she joined in 2003. She serves on the Board of Directors of Turtle & Hughes, Inc., Open Road Integrated Media, Inc., and Bergen Medical Products, Inc. In addition to C200, she is a member of the Women's Forum, Women Corporate Directors, and Women Business Leaders of the U.S. Health Care Industry Foundation. Ms. Swintek serves as the Chairperson of our Audit Committee and is a member of our Executive Compensation and Employee Benefits Committee. We believe that Ms. Swintek's qualifications to serve on our Board of Directors include her extensive expertise in finance, investment banking and venture capital and her past experience as a senior executive in the banking industry.

**LuAnn Via** has served as a member of our Board of Directors since April 2012. In November 2012 Ms. Via became 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 Board member of Christopher & Banks Corporation and 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 our 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**

We choose to separate the position of our Chief Executive Officer from that of our Chairman of the Board of Directors. Our Board of Directors has made this decision based on their belief that an independent Chairman of the Board can act as a balance to the Chief Executive Officer, who also serves as a non-independent director.

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 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. We believe an independent Chairman of the Board adds an additional layer of insight to our Board of Directors' risk oversight process.

## Compensation, Nominations 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 on Interactions with Health Care Professionals, an Anti-Fraud Program and a policy for compliance with the Foreign Corrupt Practices Act. To view the charters of our Audit, Compensation and Nominations 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](http://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 2015 that, except for Mr. Stewart, who is our Chief Executive Officer, all current members of the Board of Directors are independent under the revised listing standards of NASDAQ.

**Compensation Committee.** Our Compensation 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 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 Compensation Committee charter.

Our Board of Directors has adopted a written charter for the Compensation Committee. The Compensation Committee is currently composed of LuAnn Via, Jeffrey F. O'Donnell, Sr. and Kathryn Swintek. Ms. Via serves as the Chairman of the Compensation Committee. Our Board of Directors determined that each member of the Compensation Committee in 2015 satisfies the independence requirements of Nasdaq. The Compensation Committee held two formal meetings during 2015.

The Compensation 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 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 Committee for 2015 is presented below.

**Nominations and Corporate Governance Committee.** Our Board of Directors has established a Nominations and Corporate Governance Committee for the purpose of reviewing all Board of Director-recommended and stockholder-recommended nominees, determining each nominee's qualifications and making a recommendation to the full Board of Directors as to which persons should be our Board of Directors' nominees. Our Board of Directors has adopted a written charter for the Nominations and Corporate Governance Committee. The Nominations and Corporate Governance Committee is composed of Messrs. O'Donnell Sr., Navarro and Stone. Mr. Stone serves as the Chairman of the Nominations and Corporate Governance Committee. The Nominations and Corporate Governance Committee held two meeting during 2015 in conjunction with a meeting of the full Board of Directors.

The duties and responsibilities of the Nominations and Corporate Governance Committee include:

- identifying and recommending to our Board of Directors individuals qualified to become members of our Board of Directors;
- recommending to our Board of Directors the director nominees for the next annual meeting of stockholders;
- recommending to our Board of Directors director committee assignments;
- 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 Nominations and Corporate Governance Committee charter.

The Nominations and Corporate Governance Committee considers these requirements when recommending nominees to our Board of Directors. Our Nominations and Corporate Governance Committee utilizes a variety of methods for identifying and evaluating nominees for our directors. Our Nominations and Corporate Governance Committee will regularly assess the appropriate size of our Board of Directors and whether any vacancies on the Board of Directors are expected due to retirement or other circumstances. When considering potential director nominees, the Nominations and Corporate Governance Committee also considers the candidate's character, judgment, diversity, age, skills, including financial literacy and experience in the context of the needs of STRATA Skin and of our existing directors. The Nominations and Corporate Governance Committee also seeks director nominees who are from diverse backgrounds and who possess a range of experiences as well as a reputation for integrity. The Nominations and Corporate Governance Committee considers all of these factors to ensure that our Board of Directors as a whole possesses a broad range of skills, knowledge and experience useful to the effective oversight and leadership of the Company.

**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 the Company is 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 members of the Audit Committee are Kathryn Swintek, David K. Stone and R. Rox Anderson. Ms. Swintek serves as the Chairman of the Audit Committee. The Audit Committee meets regularly and held four meetings during 2015.

The Board of Directors determined in 2015 that each member of the Audit Committee satisfies the independence and other composition requirements of the Securities and Exchange Commission (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.

### ***Special Finance Committee***

In connection with the purchase of the XTRAC Excimer Laser and the VTRAC excimer lamp businesses from PhotoMedex, Inc. and the related 2015 Financing, the Company established a special finance committee (the "Finance Committee") for the purpose of evaluating transaction options for the Company and the potential financing for any such transaction, as well as assisting management in negotiating the acquisition of the XTRAC Excimer Laser and the VTRAC excimer lamp from PhotoMedex, Inc. and assisting management in negotiating the 2015 Financing itself. Jeffrey F. O'Donnell, Sr. and Samuel E. Navarro served on Special Finance Committee with the Board of Directors.

### ***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, Corporate Counsel at [jsturm@strataskin.com](mailto:jsturm@strataskin.com) or to the following address (our principal executive offices): Board of Directors, c/o Corporate Secretary, 100 Lakeside Drive, 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2015 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. 16, *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 audits, 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 four meetings during the fiscal year ended December 31, 2015.

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, 2015 for filing with the Commission. The audit committee has also retained EisnerAmper LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2015.

**AUDIT COMMITTEE:**

Kathryn Swintek  
R. Rox Anderson  
David K. Stone

**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 11, 2016, 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, 2015.

**Item 11. Executive Compensation**

**SUMMARY COMPENSATION TABLE**

The following table includes information for the years ended December 31, 2015 and 2014 concerning compensation for our Named Executive Officers.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u> <u>(4)</u>	<u>Stock</u> <u>Awards</u> <u>(\$)(5)</u>	<u>Option</u> <u>Awards</u> <u>(\$)(6)</u>	<u>All Other</u> <u>Compensation</u> <u>(\$)(7)</u>	<u>Total (\$)</u>
Michael R. Stewart (1), Director, President and Chief Executive Officer	2015	313,570	255,000	109,000	-	37,436	715,006
	2014	14,109	-	-	712,503	18,293	744,905
Christina L. Allgeier (2), Chief Financial Officer and Treasurer	2015	90,679	30,000	-	-	7,076	127,755
	2014	-	-	-	-	-	-
Robert W. Cook (3), Former Chief Financial Officer, Secretary and Treasurer	2015	247,450	-	-	-	208,333	455,783
	2014	179,006	15,000	-	190,000	-	384,006
Rose A. Crane (4), Former Director, President and Chief Executive Officer	2014	272,885	-	-	-	150,000	422,885

- (1) Michael R. Stewart was hired as President and Chief Executive Officer on December 15, 2014.
- (2) Christina L. Allgeier was promoted to Chief Financial Officer and Treasurer on November 9, 2015.
- (3) Robert W. Cook resigned as Chief Financial Officer, Treasurer and Secretary on November 9, 2015. He was hired as Chief Financial Officer, Treasurer and Secretary on April 14, 2014.
- (4) Rose A. Crane resigned as Director, President and Chief Executive Officer effective November 17, 2014.
- (5) Bonus in the foregoing table is the bonus earned in 2015 and 2014, even though such bonus may have been paid in a subsequent period.

- (6) The amounts shown for option awards, restricted stock awards and stock purchase rights relate to shares granted. These amounts are equal to the aggregate grant-date fair value with respect to the awards made in 2015 and 2014, computed in accordance with FASB ASC Topic 718 (formerly SFAS 123R), before amortization and without giving effect to estimated forfeitures. For information regarding the number of shares subject to 2015 awards, other features of those awards and the grant-date fair value of the awards, see the Grants of Plan-Based Awards Table below.
- (7) "All Other Compensation" includes car allowance of \$4,000, premiums for supplementary life and/or disability insurance of \$8,491 housing allowance of \$24,945 for Mr. Stewart. For Mr. Cook it includes severance paid to and to be from January to October 6, 2016. For Ms. Allgeier it includes car allowance of \$6,000 and 401(k) matching contributions of \$1,076. For Ms. Crane it includes severance paid from November 2014 through May 2015.

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

***Employment Agreement with Michael R. Stewart.*** On December 15, 2015 the Company entered into an Amended and Restated Employment Agreement (the "Amended Agreement") with Michael R. Stewart, President and Chief Executive Officer of the Company. The Amended Agreement (i) extends the term of Mr. Stewart's service until December 14, 2017, unless earlier terminated in accordance with the terms of the Amended Agreement; (ii) increases his base salary from \$310,000 per year to \$375,000 per year; and (iii) provides that Mr. Stewart's severance will be increased from 12 months to 18 months if his employment is terminated in connection with a Change of Control, as provided in the Amended Agreement. The Amended Agreement further provides that Mr. Stewart will continue to be eligible for an annual bonus of up to 50% of his base salary, but that any bonus for 2015 will be calculated based on his \$310,000 base salary. Under the Amended Agreement, the Company will continue to reimburse Mr. Stewart for supplemental life insurance in the coverage amount of \$1 million and supplemental disability coverage and pay Mr. Stewart an automobile allowance of \$1,000 per month. The Amended Agreement also contains customary non-competition, non-solicitation, non-disparagement and confidentiality provisions.

Concurrently with entering into the Amended Agreement, the Company's Board of Directors also awarded Mr. Stewart a special bonus in recognition of Mr. Stewart's extensive efforts in connection with the Company's acquisition of its XTRAC and VTRAC businesses from PhotoMedex, Inc., consisting of (i) \$100,000 in cash and (ii) 100,000 shares of restricted common stock. The cash portion of the special bonus is payable, and the restrictions on the stock portion of the special bonus expired, on January 6, 2016.

***Employment Agreement with Christina L. Allgeier.*** On November 11, 2015 we entered into an employment agreement with Christina L. Allgeier, our Chief Financial Officer. The agreement has a one-year initial term, subject to annual extensions thereafter. Under the terms of the agreement, Ms. Allgeier receives a base salary of \$200,000 and is eligible to receive a bonus of up to 30% of her base salary per annum, based on achievement of specified milestones, as determined by the Board of Directors following approval of the annual budget, and other objectives to be determined. In the event Ms. Allgeier's employment is terminated, without cause or in conjunction with a change of control, she will be entitled to severance equal to 12 months of her base salary. The agreement also contains a 12 month non-compete and non-solicitation period.

## 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, 2015.

### OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END TABLE

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable (2)	Number of Securities Underlying Unexercised Options (#) Unexercisable (2)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)	Equity Incentive Plan Awards: Number of Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$) (1)
Michael R. Stewart	250,000	500,000	0	1.31	12/15/2024	0	0	N/A	N/A
	0	N/A	0	N/A	N/A	0	0	100,000	111,000

(1) The market value of unvested shares of restricted stock is based on \$1.11 per share, which was the closing price of our stock on December 31, 2015.

(2) All options grants were under the 2013 Equity Plan.

Mr. Stewart vests in the options at 375,000 shares vesting in three equal installments on December 15, 2015, 2016 and 2017, respectively; 125,000 vesting in three equal installments upon achieving a revenue plan established by the Board of Directors on December 15, 2015, 2016, and 2017, respectively; 125,000 vesting in three equal installments upon achieving an EBITDA plan established by the Board of Directors on December 15, 2015, 2016, and 2017, respectively; and 125,000 vesting in three equal installments upon achieving goals established by the Board of Directors on December 15, 2015, 2016, and 2017, respectively.

## Director Compensation

Each of our non-employee directors receives an annual fee of \$35,000 for serving as a director, pro-rated to the date they join the Board of Directors, and an annual grant of stock options to purchase up to 75,000 shares of common stock, which grant is pro-rated to the first day of the quarter during which they join the Board of Directors. In addition, our Chairman of the Board receives an annual fee of \$25,000 and the chairman of each of our audit committee, our compensation committee and our nominating and corporate governance committee receives an annual fee of \$15,000, \$10,000 and \$10,000, respectively. Committee members who are not chairs of each of our audit committee, our compensation committee and our nominating and corporate governance committee receive, annual fees of \$6,000, \$5,000 and \$5,000, respectively, with no payments being made on a meeting-attended basis. As an employee of the Company, Michael Stewart received no compensation for his services as a director after December 14, 2014. The table below sets forth our non-employee directors' compensation through December 31, 2015.

On November 4, 2015, we entered into consulting agreements with two of our directors, Jeffrey F. O'Donnell, Sr. and Samuel E. Navarro, the terms of which are the same. Under the terms of their respective agreements, each director agrees provide strategic support, advice and guidance to us and our management team in connection with the integration and operation of our expanded business, investor relations and internal and external business development activities. The consultant will make himself available to our President and Chief Executive Officer and our management team on request at mutually convenient times and will report to our Board of Directors quarterly and otherwise when requested by the Board. The term of the agreement is from November 4, 2015 through June 30, 2016. The directors are each to be paid an up-front fee of \$40,000 for advice and services rendered prior to the date of the agreement, a retainer of \$10,000 per month, commencing November 10, 2016 and continuing on the tenth day of each month through June 10, 2016, and reimbursement of pre-approved, out-of-pocket expenses.

#### **DIRECTOR COMPENSATION TABLE**

<b>Name</b>	<b>Fees Earned (\$)</b>	<b>Stock Awards (\$ (1))</b>	<b>All Other Compensation (\$ (2))</b>	<b>Total (\$)</b>
Jeffrey F. O'Donnell, Sr.	70,000	455,653	60,000	585,653
Samuel E. Navarro	44,500	455,653	60,000	560,153
David K. Stone	51,000	42,166	0	93,166
Kathryn Swintek	55,000	42,166	0	97,166
LuAnn Via	45,000	42,166	0	87,166
R. Rox Anderson (3)	10,250	73,178	0	83,428

- (1) The amounts shown for stock awards are equal to the aggregate grant-date fair value with respect to the stock awards for financial statement purposes.
- (2) Mr. O'Donnell Sr. and Mr. Navarro receive a monthly payment of \$10,000 for their services under a consulting agreement with the Company.
- (3) Mr. Anderson was appointed a director on September 30, 2015.

#### **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 for 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.

#### **Directors' and Officers' Liability Insurance**

We have obtained directors' and officers' liability insurance, which expires on November 16, 2016. 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 Annual Report under the heading “Securities Authorized for Issuance Under Equity Compensation Plans” is hereby incorporated by reference.

The following table reflects, as of March 11, 2016, 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 <sup>(1)</sup>	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned <sup>(1)</sup>
Michael R. Stewart <sup>(2)</sup>	350,000	3.25%
Christina L. Allgeier <sup>(3)</sup>	-	*
Jeffrey F. O'Donnell, Sr. <sup>(4)</sup>	579,271	5.23%
Samuel E. Navarro <sup>(5)</sup>	576,379	5.20%
David K. Stone <sup>(6)</sup>	85,028	*
Kathryn Swintek <sup>(7)</sup>	84,128	*
LuAnn Via <sup>(8)</sup>	81,325	*
R. Rox Anderson <sup>(9)</sup>	37,500	*
All directors and officers as a group (eight persons) <sup>(10)</sup>	1,793,631	14.71%
Broadfin Healthcare Master Fund, Ltd <sup>(11)</sup>	1,008,297	9.99%
Sabby Healthcare Master Fund, Ltd <sup>(12)</sup>	782,391	9.99%
Sabby Volatility Warrant Master Fund, Ltd <sup>(13)</sup>	340,470	9.99%

\* 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 11, 2016, 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 10,503,393 shares of common stock outstanding as of March 11, 2016.
- (2) Includes 100,000 shares of common stock and vested options to purchase 250,000 shares of common stock. Does not include options to purchase up to 500,000 shares of common stock, which may vest more than 60 days after March 11, 2016.
- (3) Does not include any shares of common stock or options to purchase shares of common stock.
- (4) Includes 1,352 shares of common stock and vested options to purchase 577,919 shares of common stock. Does not include unvested options to purchase up to 75,000 shares of common stock, which may vest more than 60 days after March 11, 2016. Mr. O'Donnell's address is 100 Lakeside Drive, Suite 100, Horsham, PA 19044.
- (5) Includes vested options to purchase 576,379 shares of common stock. Does not include unvested options to purchase up to 75,000 shares of common stock, which may vest more than 60 days after March 11, 2016. Mr. Navarro's address is 100 Lakeside Drive, Suite 100, Horsham, PA 19044.

- (6) Includes 1,352 shares of common stock and vested options to purchase 83,676 shares of common stock. Does not include unvested options to purchase up to 75,000 shares of common stock, which may vest more than 60 days after March 11, 2016. Mr. Stone's address is 100 Lakeside Drive, Suite 100, Horsham, PA 19044.
- (7) Includes 3,352 shares of common stock and vested options to purchase 80,776 shares of common stock. Does not include unvested options to purchase up to 75,000 shares of common stock, which may vest more than 60 days after March 11, 2016. Ms. Swintek's address is 100 Lakeside Drive, Suite 100, Horsham, PA 19044.
- (8) Includes 1,352 shares of common stock and vested options to purchase 79,973 shares of common stock. Does not include unvested options to purchase up to 75,000 shares of common stock, which may vest more than 60 days after March 11, 2016. Ms. Via's address is 100 Lakeside Drive, Suite 100, Horsham, PA 19044.
- (9) Includes vested options to purchase 37,500 shares of common stock. Does not include unvested options to purchase up to 75,000 shares of common stock, which may vest more than 60 days after March 11, 2016. Mr. Anderson's address is 100 Lakeside Drive, Suite 100, Horsham, PA 19044.
- (10) Includes 107,408 shares of common stock and vested options to purchase 1,686,223 shares of common stock. Does not include unvested options to purchase up to 1,050,000 shares of common stock, which may vest more than 60 days after March 11, 2016.
- (11) 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) 1,008,297 shares of common stock; (ii) warrants to purchase 4,759,736 shares of common stock at \$0.75 per share; (iii) 377,177 shares of common stock issuable upon conversion of \$967,459 principal amount of 4% convertible debentures issued in July 2014 and (iv) 20,000,000 shares of common stock issuable upon conversion of \$15,000,000 principal amount of 2.25% convertible debentures issued in June 2015. The conversion of all debentures and the exercise of all warrants referenced in this footnote are subject to a 9.99% blocker. The foregoing information has been derived in part from a Schedule 13G filed by Broadfin Capital, LLC on August 24, 2015 and a Form 4 filed by Broadfin Capital LLC on March 14, 2016.
- (12) The business address of Sabby Healthcare Master Fund Ltd. ("Sabby HMF") is c/o Sabby Management LLC, 10 Mountainview Road, Suite 205, Upper Saddle River, NJ 07458. Sabby Management, LLC serves as the investment manager of Sabby HMF. Hal Mintz is the manager of Sabby Management, LLC and has voting and investment control of the securities held by Sabby HMF. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities beneficially owned by Sabby HMF except to the extent of their respective pecuniary interest therein. Sabby HMF holds the following securities: (i) 782,391 shares of common stock; (ii) warrants to purchase 7,185,717 shares of common stock at \$0.75 per share; (iii) 2,339,182 upon conversion of \$6,000,000 of Series B convertible preferred stock; (iv) 2,183,603 shares of common stock issuable upon conversion of \$5,600,941 principal amount of 4% convertible debentures issued in July 2014 and (v) 16,000,000 shares of common stock issuable upon conversion of \$12,000,000 principal amount of 2.25% convertible debentures issued in June 2015. The conversion of all debentures and the exercise of all warrants referenced in this footnote are subject to a 9.99% blocker. The foregoing information has been derived in part from a Schedule 13G filed by Sabby HMF on January 6, 2016.

- (13) The business address of Sabby Volatility Warrant Master Fund Ltd. (“Sabby VWMF”) is c/o Sabby Management LLC, 10 Mountainview Road, Suite 205, Upper Saddle River, NJ 07458. Sabby Management, LLC serves as the investment manager of Sabby VWMF. Hal Mintz is the manager of Sabby Management, LLC and has voting and investment control of the securities held by Sabby VWMF. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities beneficially owned by Sabby VWMF except to the extent of their respective pecuniary interest therein. Sabby VWMF holds the following securities: (i) 340,470 shares of common stock; (ii) warrants to purchase 2,153,810 shares of common stock at \$0.75 per share; (iii) 196,687 upon conversion of \$504,500 of Series B convertible preferred stock; (iv) 837,048 shares of common stock issuable upon conversion of \$2,147,028 principal amount of 4% convertible debentures issued in July 2014 and (v) 6,416,667 shares of common stock issuable upon conversion of \$4,812,500 principal amount of 2.25% convertible debentures issued in June 2015. The conversion of all debentures and the exercise of all warrants referenced in this footnote are subject to a 9.99% blocker. The foregoing information has been derived in part from a Schedule 13G filed by Sabby VWMF on January 6, 2016.

### **Item 13. Certain Relationships and Related Transactions, Director Independence**

#### Related Person Transactions

On June 22, 2015, we entered into a securities purchase agreement with the Purchasers, including certain funds managed by Sabby Management, LLC and Broadfin Capital LLC, in connection with a private placement. We sold \$10.0 million aggregate principal amount of Notes bearing interest at 9% per year, with a maturity date of the earlier of 30 days after the Company obtains stockholder approval of stock issuances under the Debentures and the Warrants or November 30, 2015. The Purchasers of the Notes were issued Warrants to purchase an aggregate of 3.0 million shares of common stock, having an exercise price of \$0.75 per share. We also issued \$32.5 million aggregate principal amount of Debentures that, subject to certain ownership limitations and stockholder approval conditions, will be convertible into 43,333,334 shares of common stock at an initial conversion price of \$0.75 per share. The Debentures bear interest at the rate of 2.25% per year, and, unless previously converted, will mature on the five-year anniversary of the date of issuance. Our obligations under the Debt Securities are secured by a first priority lien on all of our assets, except for a second lien on our intellectual property. As a condition of the new term note facility, the Debentures from both the 2014 and 2015 financings were amended. The Debentures holders’ first priority lien was subordinated to the new term note facility. Additionally, as a condition of the term note facility, the maturity date of both Debentures was extended to June 30, 2021. Effective upon the date the Stockholder Approval, on September 30, 2015, we repriced outstanding Warrants held by certain investors to reduce the exercise price to \$0.75 per share.

In connection with this financing, we also granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Debentures and the Warrants pursuant to the terms of the Registration Rights Agreement. In addition to the registration rights, the Selling Stockholders are entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, becoming effective and maintaining an effective registration statement covering the shares underlying the Debentures and the Warrants. The liquidated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquidated damages payable is equal to 2.0% of the aggregate purchase price paid by each Purchaser, provided, however, the maximum aggregate liquidated damages payable to a Purchaser shall be 12% of the aggregate subscription amount paid by such Purchaser pursuant to the Purchase Agreement. The liquidated damages shall accrue interest at a rate of 12% per annum (or such lesser maximum amount that is permitted to be paid by applicable law), accruing on a daily basis for each event until such event is cured.

The Registration Rights Agreement requires us to file one or more registration statements for all of the securities that may be issued upon conversion of the Debentures and exercise of the Warrants issued to the Purchasers. Pursuant to the applicable transaction documents, however, certain Purchasers may not exercise their conversion/exercise rights for that number of shares of common stock which, together with all other shares owned by that Purchaser and its affiliates would result in more than 9.99% of our issued and outstanding shares of common stock calculated on the basis of the then outstanding shares.

### Director Independence

As required under the NASDAQ Stock Market LLC, or 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 all of our current directors are independent directors within the meaning of the applicable NASDAQ listing standards, except for Mr. Stewart, who as our Chief Executive Officer, who are not independent director by virtue of his or employment with our company.

### Director Consulting Agreements

On November 4, 2015, we entered into consulting agreements with two of our directors, Jeffrey F. O'Donnell, Sr. and Samuel E. Navarro, the terms of which are the same. Under the terms of their respective agreements, each director agrees provide strategic support, advice and guidance to us and our management team in connection with the integration and operation of our expanded business, investor relations and internal and external business development activities. The consultant will make himself available to our President and Chief Executive Officer and our management team on request at mutually convenient times and will report to our Board of Directors quarterly and otherwise when requested by the Board. The term of the agreement is from November 4, 2015 through June 30, 2016. The directors are each to be paid an up-front fee of \$40,000 for advice and services rendered prior to the date of the agreement, a retainer of \$10,000 per month, commencing November 10, 2015 and continuing on the tenth day of each month through June 10, 2016, and reimbursement of pre-approved, out-of-pocket expenses.

### **Item 14. Principal Accounting Fees and Services**

We engaged EisnerAmper LLP as our independent auditors for 2015 and 2014.

The following table shows the fees paid or accrued by us for the audit and other services provided by EisnerAmper for 2015 and 2014:

	<u>2015</u>	<u>2014</u>
Audit Fees <sup>(1)</sup>	\$ 411,939	\$ 243,440
Audit-Related Fees <sup>(2)</sup>	-	-
Tax Fees <sup>(3)</sup>	70,000	35,200
All Other Fees <sup>(4)</sup>	-	-
Total	<u>\$ 481,939</u>	<u>\$ 278,640</u>

(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.

(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, principally related to the registration statements for equity and debt financings in each of 2015 and 2014.

(3) Consists of all tax related services.

(4) There were no other fees billed by EisnerAmper LLP for the years ended December 31, 2015 and 2014.

***Engagement of the Independent Auditor.*** The Audit Committee is responsible for approving every engagement of EisnerAmper LLP to perform audit or non-audit services for us before EisnerAmper 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 EisnerAmper 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 2016*** The Audit Committee has selected EisnerAmper LLP to serve as our independent auditors for the year ending December 31, 2016. The Committee's selection will be submitted to our stockholders for ratification at our 2016 Annual Meeting of Stockholders.

## **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, 2015 and 2014, and the related consolidated statements of comprehensive loss, changes in' equity and cash flows for each of the years in the two-year period ended December 31, 2015.

#### (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, as amended (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, 2014).
- 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).
- 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 3.1 contained in our Current Report on Form 8-K, filed on January 22, 2016).
- 4.14 Form of Incentive Stock Option Agreement. (Filed herewith.)
- 4.15 Form of Nonqualified Stock Option Agreement. (Filed herewith.)
- 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 14, 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 14, 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 14, 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 14, 2015).
- 10.29\* 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).
- 10.30\* 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).
- 10.31 Credit and Security Agreement dated as of December 30, 2015 among MidCap, as administrative agent, the Lenders listed on the Credit Facility Schedule attached thereto and the Company. (Incorporated by reference to Exhibit 10.1 contained in our Current Report on Form 8-K, as filed on January 5, 2016).
- 10.32 Warrant to purchase shares of the Company's common stock issued December 30, 2015 issued to MidCap. (Incorporated by reference to Exhibit 10.2 contained in our Current Report on Form 8-K, as filed on January 5, 2016).
- 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.).
23.1	Consent of EisnerAmper 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 Quarterly Report on Form 10-Q 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.

## AVAILABLE INFORMATION

We are a reporting company and file annual, quarterly and special reports, proxy statements and other information with the Commission. You may inspect and copy these materials at the Public Reference Room maintained by the Commission at Room 100 F Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for more information on the Public Reference Room. You can also find our Commission filings at the Commission's website at [www.sec.gov](http://www.sec.gov). You may also inspect reports and other information concerning us at the offices of the Nasdaq Stock Market at 1735 K Street, N.W., Washington, D.C. 20006. We intend to furnish our stockholders with annual reports containing audited financial statements and such other periodic reports as we may determine to be appropriate or as may be required by law.

Our primary Internet address is [www.strataskin sciences.com](http://www.strataskin sciences.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). Corporate information can be located by clicking on the "Investor Relations" link in the top-middle of the page, and then clicking on "SEC Filing" in the menu. We make our periodic Commission Reports (Forms 10-Q and Forms 10-K) and current reports (Form 8-K) available free of charge through our Web site as soon as reasonably practicable after they are filed electronically with the Commission. We may from time to time provide important disclosures to investors by posting them in the Investor Relations section of our Web site, as allowed by Commission's rules. The information on the website listed above is not and should not be considered part of this Annual Report on Form 10-K and is intended to be an inactive textual reference only.

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.

Date: March 15, 2016

By: /s/ Michael R. Stewart

Michael R. Stewart

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.

<u>Signature</u>	<u>Capacity in Which Signed</u>	<u>Date</u>
<u>/s/ Jeffrey F. O'Donnell, Sr.</u> Jeffrey F. O'Donnell, Sr.	Chairman of the Board of Directors	March 15, 2016
<u>/s/ Michael R. Stewart</u> Michael R. Stewart	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2016
<u>/s/ Christina L. Allgeier</u> Christina L. Allgeier	Chief Financial Officer (Principal Financial Officer)	March 15, 2016
<u>/s/ R. Rox Anderson</u> R. Rox Anderson	Director	March 15, 2016
<u>/s/ Samuel E. Navarro</u> Samuel E. Navarro	Director	March 15, 2016
<u>/s/ David K. Stone</u> David K. Stone	Director	March 15, 2016
<u>/s/ Kathryn Swintek</u> Katheryn Swintek	Director	March 15, 2016
<u>/s/ LuAnn Via</u> LuAnn Via	Director	March 15, 2016

STRATA SKIN SCIENCES, INC. AND SUBSIDIARY

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of STRATA Skin Sciences, Inc. and Subsidiary (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of STRATA Skin Sciences, Inc., and Subsidiary as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP  
New York, New York  
March 15, 2016

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

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,303	\$ 11,434
Restricted cash	15	-
Accounts receivable	4,068	220
Inventories	4,128	5,275
Prepaid expenses and other current assets	465	274
Total current assets	11,979	17,203
Property and equipment, net	13,851	1,961
Patents and licensed technologies, net	7,247	37
Other intangible assets, net	7,980	-
Goodwill	8,928	-
Deferred financing costs	1,293	821
Other assets	94	48
Total assets	\$51,372	\$ 20,070
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Note payable	\$ 299	\$ -
Accounts payable (includes \$0 and \$74 due to related parties, respectively)	4,446	1,185
Other accrued liabilities	2,161	959
Deferred revenues	173	43
Total current liabilities	7,079	2,187
Long-term liabilities:		
Long-term debt	10,179	-
Senior secured convertible debentures, net	10,804	5,001
Warrant liability	7,042	499
Deferred tax liability	119	-
Other liabilities	62	107
Total liabilities	35,285	7,794
Commitment and contingencies		
Stockholders' equity:		
Preferred Stock, \$.10 par value, 10,000,000 shares authorized; 6,505 and 11,787 shares issued and outstanding, respectively	1	1
Common Stock, \$.001 par value, 150,000,000 shares authorized; 10,283,393 and 6,037,232 shares issued and outstanding, respectively	10	6
Additional paid-in capital	223,315	194,562
Accumulated deficit	(207,240)	(182,293)
Accumulated other comprehensive income	1	-
Total stockholders' equity	16,087	12,276
Total liabilities and stockholders' equity	\$51,372	\$20,070

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

STRATA SKIN SCIENCES, INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
(In thousands, except share and per share amounts)

	For the Year Ended December 31,	
	2015	2014
Revenues	\$ 18,495	\$ 915
Cost of revenues	13,719	4,935
Gross profit (loss)	4,776	(4,020)
Operating expenses:		
Engineering and product development	2,029	1,641
Selling and marketing	9,194	3,140
General and administrative	10,028	7,821
	21,251	12,602
Loss from operations	(16,475)	(16,622)
Other income (expense), net:		
Interest expense, net	(10,200)	(2,372)
Change in fair value of warrant liability	1,814	8,103
Gain on sale of assets	-	16
Registration rights liquidated damages	-	(3,420)
Other income, net	33	150
	(8,353)	2,477
Loss before income taxes	( 24,828)	( 14,145)
Income tax expense	119	-
Net loss	( 24,947)	( 14,145)
Deemed dividend related to warrant modification	( 2,962)	( 1,887)
Net loss attributable to common stockholders	(\$ 27,909)	(\$ 16,032)
Basic and diluted net loss per share	(\$ 3.27)	(\$ 3.03)
Shares used in computing basic and diluted net loss per share	8,536,699	5,295,929
Other comprehensive loss:		
Foreign currency translation adjustments	\$ 1	\$ -
Comprehensive loss	(\$ 27,908)	(\$ 16,032)

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

STRATA SKIN SCIENCES, INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014  
(In thousands, except share and per share amounts)

	Convertible Preferred Stock						Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Series A		Series B		Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, January 1, 2014	-	\$ -	-	\$ -	4,750,159	\$ 5	\$ 176,439	(\$ 168,148)	\$ -	\$ 8,296
Issuance of Series A convertible preferred stock and common stock (net of issuance costs of \$992)	12,300	1	-	-	20,270	-	11,457	-	-	11,458
Issuance of warrants	-	-	-	-	-	-	(5,585)	-	-	(5,585)
Issuance of Series B convertible preferred stock	-	-	12,300	1	-	-	-	-	-	1
Expenses related to the issuance of Series B convertible preferred stock	-	-	-	-	-	-	(103)	-	-	(103)
Warrants and beneficial conversion feature issued with senior secured debentures	-	-	-	-	-	-	10,353	-	-	10,353
Redemption of Series A convertible preferred stock	(12,300)	(1)	-	-	-	-	-	-	-	(1)
Beneficial conversion feature related to Series B convertible preferred stock	-	-	-	1,887	-	-	(1,887)	-	-	-
Accretion of discount on Series B convertible preferred stock	-	-	-	(1,887)	-	-	1,887	-	-	-
Conversion of Series B convertible preferred stock	-	-	(513)	-	200,000	-	-	-	-	-
Conversion of senior secured convertible debentures	-	-	-	-	619,490	1	1,588	-	-	1,589
Exercise of prefunded warrants	-	-	-	-	434,325	-	-	-	-	-
Share-based compensation	-	-	-	-	12,988	-	413	-	-	413
Net loss	-	-	-	-	-	-	-	(14,145)	-	(14,145)
Balance, December 31, 2014	-	-	11,787	1	6,037,232	6	194,562	( 182,293)	-	12,276
Stock-based compensation	-	-	-	-	100,000	-	1,753	-	-	1,753
Conversion of convertible preferred stock	-	-	(5,282)	-	2,059,455	2	(2)	-	-	-
Conversion of senior secured convertible debentures	-	-	-	-	2,086,706	2	4,813	-	-	4,815
Discount on senior secured convertible debentures	-	-	-	-	-	-	27,300	-	-	27,300
Reclassification of warrant liability from stockholders' equity	-	-	-	-	-	-	(5,399)	-	-	(5,399)
Deemed dividend contribution to additional paid-in capital	-	-	-	-	-	-	2,962	-	-	2,962
Deemed dividend distribution from additional paid-in capital	-	-	-	-	-	-	(2,962)	-	-	(2,962)
Warrants issued in connection with debt	-	-	-	-	-	-	321	-	-	321
Registration costs	-	-	-	-	-	-	(33)	-	-	(33)
Other comprehensive income	-	-	-	-	-	-	-	-	1	1
Net loss	-	-	-	-	-	-	-	(24,947)	-	(24,947)
Balance, December 31, 2015	-	\$ -	6,505	\$ 1	10,283,393	\$ 10	\$ 223,315	(\$ 207,240)	\$ 1	\$ 16,087

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,	
	2015	2014
<b>Cash Flows From Operating Activities:</b>		
Net loss	(\$ 24,947)	(\$ 14,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,051	1,790
Provision for doubtful accounts	20	52
Stock-based compensation	1,753	413
Deferred taxes	119	-
Gain on disposal of property and equipment	-	(16)
Impairment of long-lived assets	920	-
Amortization of debt discount	8,479	1,943
Amortization of deferred financing costs	391	191
Inventory write-offs	4,818	1,084
Change in fair value of warrant liability	(1,814)	(8,103)
Changes in operating assets and liabilities:		
Restricted cash	(15)	-
Accounts receivable	(186)	(215)
Inventories	(508)	(784)
Prepaid expenses and other assets	(139)	606
Accounts payable and accrued expenses	542	(241)
Other accrued liabilities	92	-
Other liabilities	(80)	(46)
Deferred revenues	(81)	(238)
<b>Net cash used in operating activities</b>	<b>(6,585)</b>	<b>(17,709)</b>
<b>Cash Flows From Investing Activities:</b>		
Lasers placed-in-service, net	(1,689)	-
(Purchases) proceeds on sale of property and equipment	(35)	17
Acquisition of a business, net of cash acquired of \$0	(42,500)	-
<b>Net cash (used in) provided by investing activities</b>	<b>(44,224)</b>	<b>17</b>

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, unaudited)

	For the Year Ended December 31,	
	2015	2014
<b>Cash Flows From Financing Activities:</b>		
Proceeds from convertible debentures	32,500	15,000
Repayment of convertible debentures	(103)	-
Proceeds from senior notes	10,000	-
Repayment of senior notes	(10,000)	-
Proceeds from long-term debt	10,500	-
Payments on notes payable	(93)	-
Registration costs	(134)	-
Expenses related to financing	-	(1,115)
Proceeds from private placements/public offerings	-	11,458
<b>Net cash provided by financing activities</b>	<b>42,670</b>	<b>25,343</b>
Effect of exchange rate changes on cash	8	-
Net (decrease)/increase in cash and cash equivalents	(8,131)	7,651
Cash and cash equivalents, beginning of period	11,434	3,783
Cash and cash equivalents, end of period	\$3,303	\$11,434
<b>Supplemental information:</b>		
Cash paid for interest	\$1,188	\$ 116
<b>Supplemental information of non-cash investing and financing activities:</b>		
Modification of warrants recorded as a deemed dividend	\$ 2,962	\$ -
Beneficial conversion feature recorded as a deemed dividend	\$ -	\$ 1,887
Conversion of convertible preferred stock into common stock	\$ 5,282	\$ 513
Conversion of senior secured convertible debentures into common stock	\$ 4,815	\$ 1,589
Reclassification of property and equipment to inventory, net	\$ 107	\$ -
Reclassification of warrant liability from stockholders' equity	(\$ 5,399)	\$ -
Recognition of debt discount and beneficial conversion feature on long-term debt	\$27,300	\$10,353
Recognition of warrants issued with term note credit facility as debt discount	\$ 321	\$ -
Prepaid insurance financed with notes payable	\$ 334	\$ -
Exchange of series A convertible preferred stock for series B convertible preferred stock	\$ -	\$ 12,300
Recognition of warrants issued in connection with financings	\$ 2,958	\$ 5,585

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

STRATA SKIN SCIENCES, INC. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(In thousands, except share and per share amounts and number of lasers)

*Note 1*

**The Company:**

***Background***

STRATA Skin Sciences, Inc. (and its subsidiary) (“STRATA” or “we” or the “Company”) (formerly MELA Sciences, Inc.) is a medical technology company dedicated to developing and commercializing innovative products for the diagnosis and treatment of serious dermatological disorders. In June 2015 the Company completed the acquisition of the XTRAC Excimer Laser and the VTRAC excimer lamp businesses from PhotoMedex, Inc. which included a subsidiary in India, PhotoMedex India Ltd. The XTRAC® and VTRAC® products are FDA cleared devices for the treatment of psoriasis, vitiligo and other skin disorders. The purchase price was \$42,500 plus the assumption of certain business-related liabilities. Management believes that the cash flow generated by these businesses will be sufficient to finance the Company’s operations for the foreseeable future.

The XTRAC is an ultraviolet light excimer laser system utilized to treat psoriasis, vitiligo and other skin diseases. The XTRAC received FDA clearance in 2000 and has since become recognized treatment among dermatologists. The system delivers targeted 308nm ultraviolet light to affected areas of skin, leading to psoriasis clearing and vitiligo repigmentation, following a series of treatments. As of December 31, 2015, there were 718 XTRAC systems placed in dermatologists’ offices in the United States. The systems generate recurring revenue whereby the XTRAC system is placed in a physician’s office for no upfront charge and generates revenue on a per procedure basis. The XTRAC system’s use for psoriasis is covered by nearly all major insurance companies, including Medicare. The VTRAC Excimer Lamp system, offered internationally, provides targeted therapeutic efficacy demonstrated by excimer technology with the simplicity of design and reliability of a lamp system.

The financial results of the XTRAC and VTRAC businesses have been included in the results of operations subsequent to June 22, 2015, the date of the acquisition. The assets of the acquired businesses and liabilities assumed have been consolidated as of June 22, 2015. (See *Note 2, Acquisition.*)

To finance the purchase of the XTRAC and VTRAC businesses, in June 2015 the Company entered into a securities purchase agreement with institutional investors (the “Purchasers”) in connection with a private placement (the “2015 Financing”). The Company sold \$10,000 aggregate principal amount of Notes bearing interest at 9% per year, with a maturity date of the earlier of 30 days after the Company obtains stockholder approval of stock issuances under the Debentures and the Warrants or November 30, 2015. The matter was approved, by the stockholders’ at the Company’s annual meeting held September 30, 2015. Accordingly, the Notes matured 30 days from that approval, October 30, 2015. On December 30, 2015, the Company repaid the senior notes payable in full with the proceeds from the long-term credit facility. (See *Note 11, Long Term Debt.*) The Purchasers of the Notes were issued Warrants to purchase an aggregate of 3.0 million shares of the Company’s common stock, having an exercise price of \$0.75 per share. The Company also issued \$32,500 aggregate principal amount of Senior Secured Convertible Debentures (“Debentures”) that, subject to certain ownership limitations and stockholder approval conditions, will be convertible into 43,333,334 shares of common stock at an initial conversion price of \$0.75 per share. The Debentures bear interest at the rate of 2.25% per year, and, unless previously converted, will mature on the five-year anniversary of the date of issuance. The Company’s obligations under the Notes and Debentures (collectively, the “Debt Securities”), except for \$500 of Debentures, are secured by a subordinated lien on all of the Company’s assets. Under the terms of the Debentures and the Warrants, the issuances of shares of the common stock, including the Shares upon conversion of the Debentures and upon exercise of the Warrants, are subject to stockholder approval, which was received on September 30, 2015. Effective upon that date, the Company repriced outstanding Warrants held by certain investors to reduce the exercise price to \$0.75 per share. (See *Note 13, Warrants.*)

***Liquidity***

As of December 31, 2015, the Company had an accumulated deficit of \$207,240 and has incurred losses and negative cash flows from operations since inception. To date, the Company has dedicated most of its financial resources to research and development, sales and marketing, and general and administrative expenses.

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The Company has been dependent on raising capital from the sale of securities in order to continue to operate and to meet its obligations in the ordinary course of business. The XTRAC and VTRAC businesses, which were acquired on June 22, 2015, have had positive cash flows from operations prior to the acquisition. Management believes that its cash as of December 31, 2015 combined with the anticipated revenues from the sale of the Company's products will be sufficient to satisfy its working capital needs, capital asset purchases, outstanding commitments and other liquidity requirements associated with its existing operations through the first quarter of 2017.

***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 ("US GAAP").

***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

***Reclassification***

Certain reclassifications from the prior year presentation have been made to conform to the current year presentation. These reclassifications did not have material impact on the Company's equity, net assets, results of operations or cash flows.

***Use of Estimates***

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the US requires management to make estimates and assumptions that affect amounts reported 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, 2015, the more significant estimates include (1) revenue recognition, including deferred revenues and valuation allowances of accounts receivable, (2) the fair value of assets acquired and liabilities assumed in the business combination, (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 and (5) the valuation allowance related to deferred tax assets.

***Revenue Recognition***

The Company recognizes revenues from product sales when the following four criteria have been met: (i) the product has been delivered and the Company has no significant remaining obligations; (ii) persuasive evidence of an arrangement exists; (iii) the price to the buyer is fixed or determinable; and (iv) collection is reasonably assured. Revenues from product sales are recorded net of provisions for expected returns and cash discounts.

The Company ships most of its products FOB shipping point, although from time to time certain customers, for example governmental customers, will be granted FOB destination terms. Among the factors the Company takes into account when determining the proper time at which to recognize revenue are (i) when title to the goods transfers and (ii) when the risk of loss transfers. Shipments to distributors or physicians that do not fully satisfy the collection criteria are recognized when invoiced amounts are fully paid or fully assured and included in deferred revenues until that time.

For revenue arrangements with multiple deliverables within a single, contractually binding arrangement (usually sales of products with separately priced extended warranty), each element of the contract is accounted for as a separate unit of accounting when it provides the customer value on a stand-alone basis and there is objective evidence of the fair value of the related unit.

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The Company has two distribution channels for its phototherapy treatment equipment. The Company either (i) 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) sells its lasers through a distributor or directly to a physician. In some cases, the Company and the customer stipulate to a quarterly or other periodic target of procedures to be performed, and accordingly revenue is recognized ratably over the period.

When the Company places a laser in a physician's office, it generally recognizes revenue based on the number of patient treatments performed, or purchased under a periodic commitment, by the physician. Amounts collected with respect to treatments to be performed through laser-access codes that are sold to physicians free of a periodic commitment, but not yet used, are deferred and recognized as a liability until the physician performs the treatment. Unused treatments remain an obligation of the Company because the treatments can only be performed on Company-owned equipment. Once the treatments are performed, this obligation has been satisfied.

The Company defers substantially all revenue from sales of treatment codes ordered by its customers within the last two weeks of the period in determining the amount of procedures performed by its physician-customers. Management believes this approach closely approximates the actual amount of unused treatments that existed at the end of a period.

***Cash and Cash Equivalents***

The Company invests its excess cash in highly liquid short-term investments. The Company considers short-term investments that are purchased with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents consisted of cash and money market accounts at December 31, 2015 and 2014.

***Accounts Receivable***

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 were \$45 and \$95 at December 31, 2015 and 2014, respectively.

***Inventories***

Inventories are stated at the lower of cost or market. Cost is determined to be purchased cost for raw materials and the production cost (materials, labor and indirect manufacturing cost, including sub-contracted work components) for work-in-process and finished goods. For the Company's products, 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 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.

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Reserves for slow moving and obsolete inventories are provided based on historical experience and product demand. Management evaluates the adequacy of these reserves periodically based on forecasted sales and market trends. As of December 31, 2015 reserves on inventory were \$0. During the year ended December 31, 2015, the Company recorded a write-down of \$4,818 toward the remaining inventory value of the MelaFind® systems, raw materials and components. (See *Note 3, Inventories*.)

***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 condensed consolidated statements of comprehensive loss. Useful lives are determined based upon an estimate of either physical or economic obsolescence or both.

Management evaluates the realizability of property and equipment based on estimates of undiscounted future cash flows over the remaining useful life of the asset. If the amount of such estimated undiscounted future cash flows is less than the net book value of the asset, the asset is written down to fair value. During the year ended December 31, 2015, the Company recorded a write-down of \$920 on the remaining net book value of the MelaFind systems that were part of property and equipment (see *Impairment of Long-Lived Assets and Intangibles*).

***Patent Costs and Licensed Technologies***

Costs incurred to obtain or defend patents and licensed technologies are capitalized and amortized over the shorter of the remaining estimated useful lives or eight to 12 years. Core technology and product technology were recorded in connection with the asset purchase on June 22, 2015 and are being amortized on a straight-line basis over ten years for core technology and five years for product technology. (See *Note 5, Patent and Licensed Technologies*).

***Other Intangible Assets***

Other intangible assets were recorded in connection with the asset purchase on June 22, 2015. The assets that were determined to have definite useful lives are being amortized on a straight-line basis over ten years. Such assets primarily include customer relationships and trademarks. (See *Note 7, Other Intangible Assets*).

***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 in a business combination. The Company evaluates the carrying value of goodwill annually at the end of the calendar year 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, we may first perform an assessment qualitatively whether it is more likely than not that a reporting unit's carrying amount exceeds its fair value, referred to as a "step zero" approach. If, based on the review of the qualitative factors, we determine it is not more likely than not that the fair value of a reporting unit is less than its carrying value, we would bypass the two-step impairment test. If we conclude that it is more likely than not that a reporting unit's fair value is less than its carrying amount, we would perform the first step ("step one") of the two-step impairment test. Step 1 compares the fair value of the Group's reporting units to which goodwill was allocated to their carrying values. If the fair value of the reporting unit exceeds its carrying value, no further analysis is necessary. The reporting unit fair value is based upon consideration of various valuation methodologies, including guideline transaction multiples, multiples of current earnings, and projected future cash flows discounted at rates commensurate with the risk involved. If the carrying amount of the reporting unit exceeds its fair value, Step 2 must be completed to quantify the amount of impairment. Step 2

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calculates the implied fair value of goodwill by deducting the fair value of all tangible and intangible assets, excluding goodwill, of the reporting unit, from the fair value of the reporting unit as determined in Step 1. The implied fair value of goodwill determined in this step is compared to the carrying value of goodwill. If the implied fair value of goodwill is less than the carrying value of goodwill, an impairment loss, equal to the difference, is recognized. There was no impairment of goodwill as of December 31, 2015.

***Impairment of Long-Lived Assets and Intangibles***

Long-lived assets, such as property and equipment, 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 to the undiscounted cash flows attributable to the asset. If the carrying amount of an asset exceeds its undiscounted cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds its fair value of the asset. During the year December 31, 2015 the Company recorded a write-down of \$920 on the remaining net book value of the MelaFind systems that were part of property and equipment. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as discontinued operations are presented separately in the appropriate asset and liability sections of the balance sheet. There were no impairments recorded as of December 31, 2015 related to any of the Company's intangible assets.

***Functional Currency***

The currency of the primary economic environment in which the operations of the Company are conducted is the US dollar ("\$" or "dollars"). Thus, the functional currency of the Company is the dollar except the operations of its foreign subsidiary, which is conducted in its local currency the Indian Rupee (INR). 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 included in the statement of comprehensive loss, the exchange rates applicable to the relevant transaction dates are used. Transaction gains or losses arising from changes in the exchange rates used in the translation of such balances are carried to financing income or expenses.

Assets and liabilities of the foreign subsidiary, whose functional currency is its local currency, are translated from its functional currency to U.S. dollars at the balance sheet date exchange rate. Income and expense items are translated at the average rate of exchange prevailing during the year. Translation adjustments are reflected in the consolidated balance sheets as a component of accumulated other comprehensive loss.

***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.

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- Level 3 – pricing inputs are unobservable for the non-financial asset or liability and only used when there is little, if any, market activity for the non-financial 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 Company's recurring fair value measurements at December 31, 2015 and 2014 are as follows:

	Fair Value as of December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Liabilities:</b>				
Warrant liability (Note 13)	\$7,042	\$ -	\$ -	\$7,042
	Fair Value as of December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Liabilities:</b>				
Warrant liability (Note 13)	\$499	\$ -	\$ -	\$499

The fair value of cash and cash equivalents are based on their respective demand value, which are equal to the carrying value. The fair value of derivative warrant liabilities is estimated using option pricing models that are based on the individual characteristics of the Company's warrants, preferred and common stock, the derivative warrant liability on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate and, in some cases, credit spread. The derivative warrant liabilities are the only recurring Level 3 fair value measures. 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. The Company assessed its convertible debentures and long-term debt and determined that the fair value of total debt was \$15,958 as of December 31, 2015. As of December 31, 2014 the fair value of total debt approximated the recorded value of \$5,001.

Several of the warrants have non-standard terms as they relate to a fundamental transaction and require a net-cash settlement upon change in control of the Company and other warrants contain full ratchet provisions that reduce the exercise price of the warrants in the event of a transaction resulting in the issuance of equity below the current price of the warrants. Therefore these warrants are classified as derivatives. These warrants have been recorded at their fair value using a binomial option pricing model and will be recorded at their respective fair value at each subsequent balance sheet date. See *Note 13, 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 balance sheet. The activity in the warranty accrual during the year ended December 31, 2015 is summarized as follows:

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	December 31, 2015
Accrual at beginning of year	\$ 48
Acquired in asset purchase	265
Additions charged to warranty expense	98
Expiring warranties/claimed satisfied	(185)
Total	226
Less: current portion	(168)
	\$ 58

***Product Development Costs***

Costs of research, new product development and product redesign are charged to expense as incurred in engineering and product development.

***Advertising Costs***

Advertising costs are charged to expenses as incurred. Advertising expenses amounted to approximately \$2,500 and \$0 for the years ended December 31, 2015 and 2014, 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 and are measured using enacted tax rates and laws that are expected to be in effect when the differences reverse. Any resulting net deferred tax assets are evaluated for recoverability and, accordingly, a valuation allowance is provided when it is more likely than not that all or some portion of the deferred tax asset will not be realized.

The Company accounts for 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.

***Concentration of credit risks***

Financial instruments which subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The carrying amounts of these instruments approximate fair value due to their short-term nature. The Company deposits cash and cash equivalents in major financial institutions in the US. 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 an ongoing credit evaluation and establishes an allowance for doubtful accounts based upon factors surrounding the credit risk of customers (see also *Accounts receivable* above).

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. Accordingly, the Company's trade receivables do not represent a substantial concentration of credit risk.

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***Earnings Per Share***

Basic net loss per common share excludes dilution for potentially dilutive securities and is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share gives effect to dilutive options, warrants and other potential common shares outstanding during the period and their potential diluted effect is considered using the treasury method.

For the years ended December 31, 2015 and 2014, diluted net loss per common share is equal to the basic net loss per common share since all potentially dilutive securities are anti-dilutive. The loss on the change in fair value of the warrant liability would be considered in the diluted earnings per share calculation and was deemed to be antidilutive. Potential common stock equivalents outstanding as of December 31, 2015 and 2014 consist of common stock equivalents of common stock purchase warrants, senior secured convertible debentures, convertible preferred stock and common stock options, which are summarized as follows:

	December 31,	
	2015	2014
Common stock equivalents of convertible debentures	46,435,127	5,228,465
Common stock purchase warrants	16,729,362	13,078,920
Common stock equivalents of convertible preferred stock	2,535,866	4,595,321
Common stock options	2,684,352	1,308,835
Total	68,384,707	24,211,541

***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 that is ultimately expected to vest and is recognized as operating expense over the applicable vesting period of the stock award using the graded vesting method.

***Adoption of New Accounting Standards***

In April 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity (“ASU 2014-08”).

The amendments in ASU 2014-08 change the criteria for reporting discontinued operations while enhancing disclosures in this area. Under the new guidance, only disposals representing a strategic shift in operations should be presented as discontinued operations. Those strategic shifts should have a major effect on the organization’s operations and financial results. In addition, the new guidance requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations.

The provisions of ASU 2014-08 were required to be applied in a prospective manner to disposals or classifications as held for sale components of an entity that occur with annual periods beginning on or after December 15, 2014 and interim periods within those years.

The adoption of ASU 2014-08 did not have a material impact on the Company's consolidated results of operations and financial condition.

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***Recently Issued Accounting Standards***

In February 2016, the FASB issued ASU 2016-02, *Leases*. This statement requires lessees to present right-of-use assets and lease liabilities on the balance sheet. The standard is effective for public companies for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the effect the guidance will have on its financial condition and results of operations.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes, Balance Sheet Classification of Deferred Taxes* topic of the Codification. This standard requires all deferred tax assets and liabilities to be classified as non-current on the balance sheet instead of separating deferred taxes into current and non-current amounts. In addition, valuation allowance allocations between current and non-current deferred tax assets are no longer required because those allowances also will be classified as non-current. This standard is effective for public companies for annual periods beginning after December 15, 2016. The Company's deferred tax assets is provided with full valuation allowance as of December 31, 2015. As such, the Company does not expect that this standard will have a significant impact upon adoption.

In September 2015, the FASB issued ASU No. 2015-16, *"Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments."* The amendments in ASU 2015-16 require that an acquirer recognize adjustments to estimated amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined, rather than retrospectively adjusting amounts previously reported. The amendments require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the estimated amounts, calculated as if the accounting had been completed at the acquisition date. Effective for public business entities for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The amendments should be applied prospectively to adjustments to provisional amounts that occur after the effective date with earlier application permitted for financial statements that have not been issued. The Company does not believe the adoption of this ASU will have a significant impact on the condensed consolidated financial statements.

In July, 2015, The FASB issued Accounting Standards Update No. 2015-11, *Simplifying the Measurement of Inventory (Topic 330)* ("ASU 2015-11").

ASU 2015-11 outlines that inventory within the scope of its guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out (LIFO) are not impacted by the new guidance. Prior to the issuance of ASU 2015-11, inventory was measured at the lower of cost or market (where market was defined as replacement cost, with a ceiling of net realizable value and floor of net realizable value less a normal profit margin).

For a public entity, the amendments in ASU 2015-11 are effective, in a prospective manner, for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period (the first quarter of fiscal year 2017 for the Company). Early adoption is permitted as of the beginning of an interim or annual reporting period.

The Company is in the process of assessing the impact, if any, of ASU 2015-11 on its consolidated financial statements.

In May 2014, The FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09").

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.

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An entity should apply the amendments in this ASU using one of the following two methods: 1. Retrospectively to each prior reporting period presented with a possibility to elect certain practical expedients, or, 2. Retrospectively with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application. If an entity elects the latter transition method, it also should provide certain additional disclosures.

For a public entity, the amendments in ASU 2014-09 were to be effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. In July 2015, the FASB voted for a one year deferral of the effective date of ASU 2014-09 and issued an exposure draft. The new guidance will be effective for annual and interim periods beginning on or after December 15, 2017. Early application is not permitted. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements and footnote disclosures.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). ASU 2014-15 provides guidance on management's responsibility in evaluating whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). ASU 2014-15 also provides guidance related to the required disclosures as a result of management evaluation. The amendments in ASU 2014-15 are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the new guidance to determine the impact the adoption of this guidance will have on the Company's results of operations, cash flows or financial condition.

In April 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs* (Subtopic 835-30). ASU No. 2015-03 provides guidance that will require debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, in the same manner as debt discounts, rather than as an asset. The standard is effective for reporting periods beginning after December 15, 2015 and early adoption is permitted. The Company adopted this ASU effective January 1, 2016. Upon adoption of this guidance \$328 of deferred financing costs will be reclassified against long-term debt and \$966 will be reclassified against convertible debentures.

*Note 2*

**Acquisition:**

On June 22, 2015, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") with PhotoMedex Inc. and PhotoMedex Technology, Inc. pursuant to which the Company has purchased the XTRAC and VTRAC laser businesses from PhotoMedex, Inc. (the "Asset Purchase") for \$42,528 in cash and assumed certain business-related liabilities. The purchased assets include all of the accounts receivable, inventory and fixed and intangible assets of the business.

The fair value of the assets acquired and liabilities assumed were based on management estimates. The significant intangible assets to be recognized in the valuation are core and product technologies, tradenames and customer relationships. The estimated useful lives over which these assets will be amortized, utilizing the straight line method, are five years for product technologies and ten years for core technologies, tradenames and customer relationships. The following allocation of the aggregate fair value is preliminary and subject to adjustment based on the fair value of the assets acquired and the liabilities assumed. The Company estimated fair value of the intangibles and lasers placed in service was based on the income approach which estimated cash flow that utilize appropriate discount and capitalization rates and available market information. Estimates of future cash flows are based on a number of factors including the historical operating results, known trends and specific market and economic conditions. The fair value of the Company's remaining fixed assets was estimated based on the cost approach which estimated the cost to replace.

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Current assets	\$ 7,233
Property, plant and equipment	14,340
Identifiable intangible assets	16,100
Other assets	45
Total assets assumed	<u>37,718</u>
Current liabilities	(3,945)
Note payable	(57)
Other long term liabilities	(116)
Total liabilities assumed	<u>(4,118)</u>
Net assets acquired	<u>\$ 33,600</u>

The purchase price exceeded the fair value of the net assets acquired by \$8,928, which was recorded as goodwill.

The consolidated results of operations do not include any revenues or expenses related to XTRAC and VTRAC businesses on or prior to June 22, 2015, the date of the asset purchase. The Company's unaudited pro-forma results for the year ended December 31, 2015 and 2014 summarize the combined results in the following table, assuming the asset purchase had occurred on January 1, 2014 and after giving effect to the acquisition adjustments, including amortization of the tangible and long-lived intangible assets acquired in the transaction:

	Year Ended December 31,	
	<u>2015</u>	<u>2014</u>
	(unaudited)	(unaudited)
Net revenues	\$ 33,163	\$ 31,497
Net loss attributable to common shareholders	(\$ 34,252)	(\$ 26,954)
Net loss per basic and diluted share:	(\$ 4.01)	(\$ 5.09)
Shares used in calculating net loss per basic and diluted share:	8,536,699	5,295,929

These unaudited pro-forma results have been prepared for comparative purposes only and do not purport to be indicative of the results of operations which would have actually resulted had the acquisition occurred on January 1, 2014, nor to be indicative of future results of operations.

*Note 3*

**Inventories:**

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Raw materials and work in progress	\$ 3,706	\$ 2,553
Finished goods	422	4,131
Total inventories	4,128	6,684
Reserve for obsolete inventory	-	(870)
Reserve for inventory repairs	-	(539)
	<u>\$ 4,128</u>	<u>\$ 5,275</u>

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Work-in-process is immaterial, given the Company's typically short manufacturing cycle, and therefore is disclosed in conjunction with raw materials. During the year ended December 30, 2015 the Company initiated plans to develop an updated version of the MelaFind system and, accordingly, determined that a majority of its existing inventory of MelaFind systems and related parts exceeded its requirements. As a result, the Company wrote-off the excess and obsolete MelaFind inventories of \$5,688, including \$870 previously reserved. In addition, as of December 31, 2014 the Company carried a repair reserve of \$539 for the estimated cost to restore its MelaFind units to sellable condition, which was also eliminated with the write-off of the excess and obsolete MelaFind inventory.

*Note 4*

**Property and Equipment, net:**

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Lasers placed-in-service	\$ 15,783	\$ -
MelaFind systems	-	3,193
Equipment, computer hardware and software	1,219	1,084
Furniture and fixtures	2,080	1,969
Leasehold improvements	931	906
	<u>20,012</u>	<u>7,152</u>
Accumulated depreciation and amortization	(6,161)	(5,191)
Property and equipment, net	<u>\$ 13,851</u>	<u>\$ 1,961</u>

Depreciation and related amortization expense was \$3,141 and \$1,785 for the year ended December 31, 2015 and 2014, respectively. During the second quarter of 2015, the Company evaluated the future cash flows of the MelaFind devices with remaining net book value, determined there was an impairment and recorded an impairment charge of \$920.

*Note 5*

**Patents and Licensed Technologies, net:**

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Core technology	\$5,974	\$ 274
Product technology	2,000	-
	<u>7,974</u>	<u>274</u>
Accumulated amortization	(727)	(237)
Patents and licensed technologies, net	<u>\$7,247</u>	<u>\$ 37</u>

Related amortization expense was \$490 and \$5 for each of the year ended December 31, 2015 and 2014. The Core technology of \$5,700 and Product technology of \$2,000 are the core and product technologies acquired in the asset purchase of the XTRAC and VTRAC businesses and were recorded at their appraised fair values at that date. Amortization of these intangibles is on a straight-line basis over 5 years for Product technology and 10 years for Core technology.

Estimated amortization expense for amortizable patents and licensed technologies assets for the future periods is as follows:

2016	\$ 975
2017	975
2018	975
2019	975
2020	775
Thereafter	<u>2,572</u>
Total	<u>\$7,247</u>

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*Note 6*

**Goodwill:**

Goodwill reflects the value or premium of the acquisition price in excess of the fair values assigned to specific tangible and intangible assets. Goodwill has an indefinite useful life and therefore is not amortized as an expense, but is reviewed annually for impairment based on its fair value to the Company. Goodwill was recorded on the acquisition of the XTRAC and VTRAC businesses as the purchase price exceeded the net assets of the business. (See *Note 2, Acquisition.*)

Balance at January 1, 2015	\$ -
Additions for the acquisition	<u>8,928</u>
Balance at December 31, 2015	<u><u>\$ 8,928</u></u>

The Company has no accumulated impairment losses of goodwill related to its continuing operations as of December 31, 2015.

*Note 7*

**Other Intangible Assets:**

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

	<u>December 31, 2015</u>
Customer relationships	\$6,900
Tradenames	<u>1,500</u>
	8,400
Accumulated amortization	<u>(420)</u>
Other intangible assets, net	<u><u>\$7,980</u></u>

Related amortization expense was \$420 for the year ended December 31, 2015. There was no related amortization expense for the year ended December 31, 2014. Customer Relationships embody the value to the Company of relationships that PhotoMedex, for the XTRAC and VTRAC products, had formed with its customers. Trademarks include the tradenames and various trademarks associated with the products (e.g. "XTRAC" and "VTRAC"). Amortization of these intangibles is on a straight-line basis over 10 years for each of the customer relationships and tradenames. There were no other intangible assets at December 31, 2014.

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

2016	\$ 840
2017	840
2018	840
2019	840
2020	840
Thereafter	<u>3,780</u>
Total	<u><u>\$7,980</u></u>

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*Note 8*

**Other Accrued Liabilities:**

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Accrued warranty, current, see Note 1	\$ 168	\$ 48
Accrued compensation, including commissions and vacation	1,336	192
Accrued sales and other taxes	349	105
Accrued professional fees	265	98
Vendor settlement	-	282
Other accrued liabilities	<u>43</u>	<u>234</u>
Total other accrued liabilities	<u>\$ 2,161</u>	<u>\$ 959</u>

*Note 9*

**Senior Notes Payable:**

On June 22, 2015, the Company entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) and related financing documents with entities affiliated with existing institutional investors in the Company providing for the issuance of \$42,500 aggregate principal amount (the “Financing”) of senior secured notes (the “Notes”), senior secured convertible debentures, except for \$500 of Debentures, (the “June 2015 debentures”) and warrants (the “June 2015 Warrants”) to purchase 3,000,000 shares of common stock at an exercise price of \$0.75 per share. The Company sold \$10,000 aggregate principal amount of Notes bearing interest at 9% per year with a maturity date of the earlier of 30 days after the Company obtains stockholder approval of stock issuances under the Debentures and the Warrants or November 30, 2015. The June 2015 Debentures are discussed further in *Note 10, Convertible Debentures*, below. The proceeds of the Financing were used to pay the purchase price of the assets acquired under the Asset Purchase Agreement.

Under the terms of the June 2015 Warrants, the issuances of shares of the common stock upon exercise of the Warrants were subject to stockholder approval of such issuances and an amendment to the Company’s certificate of incorporation to increase the Company’s authorized shares of common stock. The matter was approved by the stockholders at the Company’s annual meeting held September 30, 2015. Accordingly, the Notes matured 30 days from that approval, October 30, 2015. On December 30, 2015, the Company repaid the senior notes payable in full with the proceeds from the long-term credit facility. (See *Note 11, Long Term Debt*.)

The June 2015 Warrants contain anti-dilution provisions that allow for downward exercise price adjustments in certain situations. The warrants were treated as a derivative liability (see *Note 13, Warrants*) and a discount to the Notes and the discount was amortized under the effective interest method over the repayment term of 5 months. The discount of \$2,958 was fully amortized through December 31, 2015.

The Company computed the value of the warrants using the binomial method. The key assumptions used to value the warrants are as follows:

	<u>June 22, 2015</u>	<u>December 31, 2015</u>
Number of shares underlying warrants	3,000,000	3,000,000
Exercise price	\$0.75	\$0.75
Share price	\$1.38	\$1.11
Fair value of warrants	\$2,959	\$1.807
Probability of stockholder approval	80.0%	100.0%
Volatility	90.0%	50.0%
Risk-free interest rate	1.62%	1.65%
Expected dividend yield	0%	0%
Expected warrant life	5 years	4.48 years

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*Note 10*

**Convertible Debentures:**

In the following table is a summary of the Company's convertible debentures.

	December 31, 2015	December 31, 2014
Senior secured 2.25% convertible debentures, net of unamortized debt discount of \$26,267	\$ 6,011	\$ -
Senior secured 4% convertible debentures, net of unamortized debt discount of \$3,922 and \$8,410, respectively	4,793	5,001
Total convertible debt	\$ 10,804	\$ 5,001

The Company issued \$32,500 aggregate principal amount of Debentures (June 2015 Debentures) that, subject to certain ownership limitations and stockholder approval conditions, will be convertible into 43,333,334 shares of Company common stock at an initial conversion price of \$0.75 per share. The Debentures bear interest at the rate of 2.25% per year, and, unless previously converted, will mature on the five-year anniversary of the date of issuance, June 22, 2020. Under the terms of the June 2015 Debentures and the June 2015 Warrants (noted above), the issuances of shares of the common stock upon conversion of the June 2015 Debentures and upon exercise of the Warrants were subject to stockholder approval of such issuances and an amendment to the Company's certificate of incorporation to increase the Company's authorized shares of common stock. The Company received stockholder approval for these proposals, at the annual stockholders meeting held September 30, 2015.

The June 2015 Debentures include a beneficial conversion feature valued at \$27,300 that was recorded as a discount to the debentures. On the date of issuance the beneficial conversion feature value was calculated as the difference resulting from subtracting the conversion price of \$0.75 from \$1.38, the opening market value of the Company's common stock following the announcement of the transaction, multiplied by the number of common shares into which the June 2015 Debentures are convertible. This discount is being amortized over the five year life of the June 2015 Debentures using the effective interest method. The embedded conversion feature contains an anti-dilution provision that allows for downward exercise price adjustments in certain situations. The embedded conversion feature was not bifurcated as it did not meet all of the elements of a derivative.

On July 21, 2014, the Company entered into a definitive Securities Purchase Agreement (the "Purchase Agreement") with institutional investors (the "Investors") providing for the issuance of Senior Secured Convertible Debentures in the aggregate principal amount of \$15,000, due, subject to the terms therein, in July 2019 (the "July 2014 Debentures"), and warrants (the "July 2014 Series A Warrants") to purchase up to an aggregate of 6,198,832 shares of common stock, \$0.001 par value per share, at an exercise price of \$2.45 per share expiring in July 2019. The July 2014 Debentures bear interest at an annual rate of 4%, payable quarterly or upon conversion into shares of common stock. The Debentures are convertible at any time into an aggregate of 5,847,955 shares of common stock at an initial conversion price of \$2.565 per share. The Company's obligations under the July 2014 Debentures are secured by a first priority lien on all of the Company's intellectual property pursuant to the terms of a security agreement ("Security Agreement") dated July 21, 2014 among the Company and the Investors. In connection with the Purchase Agreement, the Company entered into a Registration Rights Agreement with the Investors pursuant to which the Company was obligated to file a registration statement to register for resale the shares of Common Stock issuable upon conversion of the Series B Preferred Stock (See *Note 13, Warrants*) and Debentures and upon exercise of the Warrants. Under the terms of the Registration Rights Agreement, the Company filed a registration statement on August 19, 2014, which was declared effective by the SEC on October 20, 2014 (File No. 333-198249). Proceeds from the Debentures were used for general working capital purposes.

For financial reporting purposes, the \$15,000 funded by the Investors on July 21, 2014 was allocated first to the fair value of the obligation to issue the Warrants, amounting to \$5,296, then to the intrinsic value of the beneficial conversion feature on the July 2014 Debentures of \$4,565. The balance was further reduced by the fair value of warrants issued to the placement agent for services rendered of \$491, resulting in an initial carrying value of the Debentures of \$4,647. The initial debt discount on the July 2014 Debentures totaled \$10,353 and is being amortized using the effective interest method over the five year life of the July 2014 Debentures.

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During the year ended December 31, 2015, the investors converted debentures amounting to \$4,593 into 1,790,671 shares of common stock for the July 2014 note and \$222 into 296,035 shares of common stock for the June 2015 note. The debt discount and deferred financing cost adjustment resulting from the conversions increased interest expense by \$3,601 for the year ended December 31, 2015.

As a condition of the new note facility (See *Note 11*, **Long-term Debt** below) the Debentures from both the 2014 and 2015 financings were amended. The Debentures holders' first priority lien was subordinated to the new term note facility. Additionally, as a condition of the term note facility, the maturity date of both Debentures was extended to June 30, 2021. The Company evaluated the modifications to determine if there was an extinguishment of debt. Based on the valuation, the discounted cash flows did not change by more than 10%, thus they were treated as a modification.

As of December 31, 2015, the total outstanding amount of Debentures was \$40,993.

*Note 11*

**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 "Agreement") and related financing documents with MidCap Financial Trust ("MidCap") and the lenders listed therein. Under the 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 proceeds of this first tranche were used to repay \$10,000 principal amount of short-term senior secured promissory notes (See *Note 9*, **Senior Notes Payable**), plus associated interest, loan fees and expenses. The second tranche was drawn for \$1,500 on January 29, 2016. The Company's obligations under the credit facility are secured by a first priority lien on all of the Company's assets. This credit facility includes both financial and non-financial covenants, including a minimum net revenue covenant, beginning in January 2016. The Company's existing debentures from its 2014 and 2015 financings were amended as a condition of this new term note facility, including subordination agreements and maturity extensions. As of December 31, 2015 the net balance of long-term debt is \$10,179.

In connection with the issuance of the Term Note the Company issued MidCap (and the lenders) a warrant to purchase 650,442 shares of the Company's common stock for an exercise price of \$1.13. The warrant is exercisable at any time on or prior to the fifth anniversary of its issue date. The warrants are treated as a discount to the debt and are accreted under the effective interest method over the repayment term of 60 months. The Company has accounted for these warrants as equity instruments since there is no option for cash or net-cash settlement when the warrants are exercised and since they are indexed to the Company's common stock. The Company computed the value of the warrants using the Black-Scholes method. The key assumptions used to value the warrants are as follows:

	December 30, 2015
Number of shares underlying warrants	650,442
Exercise price	\$1.13
Stock price on date of issuance	\$1.11
Fair value of warrants	\$321,045
Volatility	50.0%
Risk-free interest rate	1.8%
Expected dividend yield	0%
Expected warrant life	5 years

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During December 2015 the Company changed its method of calculating expected volatility that is used in its fair value measurements and measurements of share based compensation cost. The new method estimates expected volatility by using a combination of the Company’s historical volatility since June 22, 2015, the acquisition date of the XTRAC and VTRAC businesses, plus the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term of the underlying instrument. The Company believes that this method provides for a better estimate of future volatility because of the significant change to the overall Company resulting from the acquisition of the XTRAC and VTRAC businesses on June 22, 2015. The Company had historically calculated expected volatility based solely upon the historical volatility of the Company’s daily closing stock price. Had the Company utilized the historical method of calculating volatility, the resulting volatility would have been 77% and the fair value of these warrants would have been \$439 at December 31, 2015.

*Note 12*

**Commitments and Contingencies:**

***Leases***

The Company has entered into various non-cancelable operating lease agreements for real property and three minor operating leases for personal property. These arrangements expire at various dates through 2018. Rent expense was \$748 and \$445 for the years ended December 31, 2015 and 2014, respectively. The future annual minimum payments under these leases, relating to our continuing operations are as follows:

<u>Year Ending December 31,</u>	
2016	\$ 861
2017	205
Thereafter	<u>19</u>
Total	<u><u>\$ 1,085</u></u>

*Note 13*

**Warrants:**

The Company accounts for warrants that have provisions that protect holders from a decline in the issue price of its common stock (or “down-round” provisions) as liabilities instead of equity. Down-round provisions reduce the exercise or conversion price of a warrant or convertible instrument if a company either issues equity shares for a price that is lower than the exercise or conversion price of those instruments or issues new warrants or convertible instruments that have a lower exercise or conversion price. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of physically exercising the warrant by paying cash. The Company evaluated whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a “fixed-for-fixed” option. In connection with the Senior secured notes (see *Note 9, Senior Notes Payable*), the Company issued warrants to purchase 3,000,000 shares of common stock. These warrants were classified as liabilities and had an initial fair value of \$2,958. See the table in Note 9 for the assumptions used.

As approved by the stockholders on September 30, 2015, the Company modified the terms of warrants held by the investors that participated in the June 2015 Debentures in excess of \$5 million, which included reducing the exercise price of such warrants to \$0.75 and adding down-round price protection provisions. These warrants had previously been classified and recorded in stockholders’ equity. As a result of the modification these warrants now meet the definition of a derivative. The fair value of these warrants as of September 30, 2015 was \$5,399 and have been reclassified to a warrant liability. As a result of the modification, the Company recorded a deemed dividend related to these warrants of \$2,962, which was determined as the difference between the fair value of these warrants immediately before the modification and immediately after. The Company used the binomial method to value the warrants. (See assumptions used in the table below.) The following is a listing of the warrants modified:

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Issue date	# of warrants	Original Exercise Price	New Exercise Price
7/24/14 Series A	4,288,500	\$ 2.45	\$0.75
7/24/14 Series B	4,795,321	\$ 2.45	\$0.75

The Company recognizes such warrants as liabilities at the fair value on each reporting date. The Company measured the fair value of these warrants as of December 31, 2015, and recorded other income of \$1,814 resulting from the decrease of the liability associated with the fair value of the warrants for the year ended December 31, 2015. The Company measured the fair value of these warrants as of December 31, 2014, and recorded other income of \$8,103 resulting from the decrease of the liability associated with the fair value of the warrants for the year ended December 31, 2014. The Company computed the value of the warrants using the binomial method. A summary of quantitative information with respect to the valuation methodology and significant unobservable inputs used for the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy as of December 31, 2015, September 30, 2015 and December 31, 2014 is as follows:

	December 31, 2015	September 30, 2015	December 31, 2014
Stock price	\$ 1.11	\$ 1.14	\$ 1.20
Volatility	35.90 – 50.00%	90.00%	72.90 – 88.10%
Risk-free interest rate	0.02% – 1.63%	0.02% - 1.30%	1.65%
Expected dividend yield	0%	0%	0%
Expected warrant life	0.07 – 4.48 years	0.32 – 4.73 years	4.10 – 4.33 years

*Recurring Level 3 Activity and Reconciliation*

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3). The table reflects gains and losses for the year for all financial liabilities categorized as Level 3 as of December 31, 2015.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3):

Issuance Date	January 1, 2015	Initial Measurements	Reclassified from Equity	Increase (Decrease) in Fair Value	December 31, 2015
10/31/2013	\$ 233	\$ -	\$ -	\$ 146	\$ 379
2/5/2014	266	-	-	449	715
7/24/2014 Series A	-	-	3,452	(1,037)	2,415
7/24/2014 Series B	-	-	1,947	(221)	1,726
6/22/2015	-	2,958	-	(1,151)	1,807
Total	<u>\$ 499</u>	<u>\$ 2,958</u>	<u>\$ 5,399</u>	<u>(\$ 1,814)</u>	<u>\$ 7,042</u>

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During December 2015 the Company changed its method of calculating expected volatility that is used in its fair value measurements and measurements of share based compensation cost. The new method estimates expected volatility by using a combination of the Company's historical volatility since June 22, 2015, the acquisition date of the XTRAC and VTRAC businesses, plus the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term of the underlying instrument. The Company believes that this method provides for a better estimate of future volatility because of the significant change to the overall Company resulting from the acquisition of the XTRAC and VTRAC businesses on June 22, 2015. The Company had historically calculated expected volatility based solely upon the historical volatility of the Company's daily closing stock price. Had the Company utilized the historical method of calculating volatility, the resulting volatility would have been 90% and the fair value of these warrants would have been \$8,975 at December 31, 2015.

*Note 14*

**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. There were 6,505 shares and 11,787 shares of Series B convertible preferred stock issued and outstanding on December 31, 2015 and 2014, respectively.

On February 5, 2014, pursuant to a securities purchase agreement, dated as of January 31, 2014, the Company sold an aggregate of 12,300 shares of Series A convertible preferred stock, par value \$0.10 and a stated value of \$1,000 per share convertible into 1,464,287 shares of common stock at an initial conversion price of \$8.40, and warrants to purchase up to 1,329,731 shares of common stock for net proceeds of \$11,458. The warrants have an exercise price of \$7.40 per share, are immediately exercisable and have a term of five years. These warrants have non-standard terms as they relate to a fundamental transaction and require a net-cash settlement upon a change in control of the Company and therefore are classified as a derivative liability and recorded at fair value on the inception date of February 5, 2014 and at each subsequent balance sheet date.

In connection with this financing, the Company also granted resale registration rights with respect to the shares of common stock underlying the Series A preferred stock and the warrants pursuant to the terms of a Registration Rights Agreement. The purchasers were entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, effectiveness and maintaining an effective registration statement covering the shares underlying the Series A Preferred Stock and the warrants. The Company was unable to meet certain filing and effectiveness requirements and as a result paid liquidated damages to the Purchasers in the aggregate amount of \$3,420 during the year ended December 31, 2014. Under the terms of the Registration Rights Agreement, the Company filed a registration statement on March 18, 2014, which was declared effective by the SEC on April 3, 2014.

On July 24, 2014, in connection with the July 2014 Debentures (see *Note 10, Convertible Debentures*), the Company exchanged 12,300 shares of Series A convertible preferred stock issued on February 5, 2014 with 12,300 shares of Series B convertible preferred stock at a stated value of \$1,000 per share convertible into common stock at an initial price of \$2.565 per share. The preferred stock is immediately convertible into an aggregate of 4,795,321 shares of common stock. Holders of the Series B convertible preferred stock are entitled to dividends only in the event that dividends are paid on the common stock, and the preferred stock has no preferences over the common stock. In connection with the exchange, the Company issued the July 2014 Series B warrants to purchase up to an aggregate of 4,795,321 shares of common stock at an exercise price of \$2.45 per share, expiring in January 2016. The July 2014 Series B warrants are immediately exercisable and are subject to certain ownership limitations.

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The \$12,300 preferred stock value was allocated first to the fair value of the July 2014 Series B warrants, which totaled \$2,487, then to the intrinsic value of the beneficial conversion feature of \$1,887. The amount of the beneficial conversion feature was considered to be a deemed dividend on the date of issuance to the Series B preferred stockholders. Pursuant to the terms of the Purchase Agreement, the Series A convertible preferred stock was redeemed from the proceeds of the Series B convertible preferred stock. In September 2014, the Company amended the registration statement related to the Series A preferred stock to deregister those shares that would have been issuable upon conversion of the Series A preferred stock had it not already been redeemed by the proceeds of the Series B preferred stock.

During year ending December 31, 2015, 5,282.5 shares of Series B preferred stock were converted into 2,059,455 shares of common stock.

***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 10,283,393 and 6,037,232 issued and outstanding at December 31, 2015 and 2014, respectively.

On October 29, 2013, the Company entered into a securities purchase agreement with certain accredited investors in connection with a \$6,000,000 registered offering of 422,819 shares of the Company's common stock, fully paid prefunded warrants (the "October 2013 Series B Warrants") to purchase up to 434,325 shares of its common stock and additional warrants ("October 2013 Series A Warrants") to purchase up to 685,715 shares of its common stock. The October 2013 Series A Warrants are exercisable beginning on May 1, 2014 at a price of \$8.50 per share and expire on May 1, 2019. The October 2013 Series B Warrants were exercisable immediately for no additional consideration. The offering closed on October 31, 2013. The holders exercised all of the October 2013 Series B Warrants in March 2014.

The October 2013 Series A Warrants have non-standard terms as they relate to a fundamental transaction and require a net-cash settlement upon a change in control of the Company and therefore are classified as a derivative. Therefore, these warrants have been recorded at fair value at the inception date of October 31, 2013, and will be recorded at their respective fair values at each subsequent balance sheet date.

Outstanding common stock warrants consist of the following:

Issue Date	Expiration Date	Total Warrants	Exercise Price
4/26/2013	4/26/2018	69,321	\$ 11.18
10/31/2013	4/30/2019	685,715	\$ 0.75
2/5/2014	2/5/2019	1,329,731	\$ 0.75
7/24/2014	7/24/2019	6,198,832	\$ 0.75 - \$ 2.45
7/24/2014	1/24/2016	4,795,321	\$ 0.75
6/22/2015	6/22/2020	3,000,000	\$ 0.75
12/30/2015	12/30/2020	650,442	\$ 1.13
		16,729,362	

*Note 15*

**Stock-based compensation:**

***Stock Options***

On April 25, 2013, the Company's stockholders approved the Company's adoption of the new 2013 Stock Incentive Plan ("2013 Plan") having 3,500,000 shares available for issuance in respect of awards made thereunder. On September 30, 2015, the Company's stockholders approved an increase in the shares available for issuance from 3,500,000 to 13,250,000. The Company terminated the 2005 Stock Incentive Plan in December 2014. As of December 31, 2015, the aggregate number of shares of common stock remaining available for issuance for awards under the 2013 Plan totaled 10,565,648.

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A summary of option transactions for all of the Company's stock options during the years ended December 31, 2015 and 2014 follows:

	Number of Stock Options	Weighted Average Exercise Price
Outstanding at December 31, 2013	306,616	\$16.20
Granted	1,205,162	1.70
Exercised	-	-
Expired/cancelled	(202,943)	16.74
Outstanding at December 31, 2014	1,308,835	2.76
Granted	1,487,500	1.15
Exercised	-	-
Expired/cancelled	(111,983)	10.70
Outstanding at December 31, 2015	2,684,352	\$ 1.54
Exercisable at December 31, 2015	1,729,177	\$ 1.66
Options expected to vest at December 31, 2015	952,850	\$ 1.26

The outstanding and exercisable options at December 31, 2015, have a range of exercise prices and associated weighted remaining contractual life and weighted average exercise price, as follows:

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 Avg. Exercise Price
\$0 - \$1.25	1,487,500	9.80	\$ 1.15	1,037,500	\$ 1.14
\$1.26 - \$5.00	1,125,000	8.95	1.40	625,000	1.47
\$5.01 - \$10.00	53,402	7.92	6.75	50,352	6.74
\$10.01 - \$63.00	18,450	6.62	25.95	16,325	26.54
Total	2,684,352	9.38	\$ 1.54	1,729,177	\$ 1.66

As the share price as of December 31, 2015 was \$1.11, the aggregate intrinsic value for options outstanding and exercisable was immaterial.

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. 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,	
	2015	2014
Risk-free interest rate	1.80 - 1.90%	2.14 - 2.45%
Volatility	50.00 - 85.68%	75.51 - 73.87%
Expected dividend yield	0%	0%
Expected life	6.5 years	6.5 years
Estimated forfeiture rate	0%	0%

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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. The expected volatility assumptions were determined based upon the historical volatility of the Company's daily closing stock price. 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 December 15, 2015, the Company issued 100,000 shares of restricted stock to its Chief Executive Officer. The restricted shares have a purchase price of \$0.01 per share and vest, and cease to be subject to the Company's right of repurchase, on January 5, 2016. The Company determined the fair value of the awards to be the fair value of the Company's common stock units on the date of issuance less the value paid for the award. The aggregate fair value of these restricted stock issued was \$109.

On December 1, 2015, the Company granted an aggregate of 450,000 options to purchase common stock to the non-employee board directors with a strike price of \$1.18. The options vest over a one year period and expire ten years from the date of grant. The aggregate fair value of the options granted was \$253. During December 2015 the Company changed its method of calculating expected volatility that is used in its fair value measurements and measurements of share based compensation cost. The new method estimates expected volatility by using a combination of the Company's historical volatility since June 22, 2015, the acquisition date of the XTRAC and VTRAC businesses, plus the historical volatility of stocks of similar publicly-traded companies for a period matching the expected term of the underlying instrument. The Company believes that this method provides for a better estimate of future volatility because of the significant change to the overall Company resulting from the acquisition of the XTRAC and VTRAC businesses on June 22, 2015. The Company had historically calculated expected volatility based solely upon the historical volatility of the Company's daily closing stock price. Had the Company utilized the historical method of calculating volatility, the resulting volatility would have been 85.19% and the fair value of these warrants would have been \$384 at December 31, 2015.

On September 30, 2015, the Company issued 37,500 to a new board director with a strike price of \$1.14. The options vest on December 1, 2015 and expire ten years from the date of grant. The aggregate fair value of the options granted was \$31.

On September 30, 2015, the Company granted an aggregate of 1,000,000 options to purchase common stock to two board directors, for their service on the finance committee of the Board of Directors, with a strike price of \$1.14. The options vested immediately and expire ten years from the date of grant. The aggregate fair value of the options granted was \$826.

Stock-based compensation expense, primarily included in general and administration, for the years ended December 31, 2015 and 2014 was \$1,753 and \$413, respectively. The year ended December 31, 2014, also included \$20 of non-employee stock-based compensation. As of December 31, 2015 there was \$635 in unrecognized compensation expense, which will be recognized over a weighted average period of 1.1 years.

*Note 16*

**Income Taxes:**

The Company accounts for income taxes using the asset and liability method for deferred income taxes.

The provision for income taxes includes federal, state and local income taxes currently payable and deferred taxes resulting from 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 more likely than not that a tax benefit will not be realized.

The Company provides for income taxes offset by changes in valuation allowances.

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The difference between the actual income tax benefit and that computed by applying the U.S. federal income tax rate of 34% to pretax loss from continuing operations is summarized below:

	For the Years Ended December 31,	
	2015	2014
Computed expected tax benefit	(\$ 8,472)	(\$ 4,270)
State tax benefit, net of federal effect	(1,365)	(217)
Net increase in valuation allowance	9,956	4,487
Provision for income taxes	\$ 119	\$ -

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities as of December 31, 2015 and 2014 are as follows:

	December 31,	
	2015	2014
Deferred tax assets/(liabilities):		
Net operating loss carryforward	\$ 64,075	\$ 57,367
Capitalized research and developmental costs	10,543	12,925
Inventory	47	689
Reserves & accrued expenses	3,295	135
Warrant liability	-	(3,123)
Convertible debt discount	(11,182)	-
Property & equipment	(355)	(785)
Non-cash compensation	1,054	3,840
Goodwill	(119)	-
Total deferred tax assets	67,358	71,048
Less: valuation allowance	(67,477)	(71,048)
Net deferred tax assets/(liabilities)	\$ (119)	\$ -

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, a full valuation allowance has been recorded against the deferred tax assets as of December 31, 2015 and 2014. The Company's valuation allowance against its deferred tax assets decreased by \$3,571 for the year ended December 31, 2015 and increased by \$4,487 for the year ended December 31, 2014.

At December 31, 2015 and 2014, the Company has federal net operating loss carryforwards of approximately \$161,693 and \$144,759, respectively, to offset future taxable income. 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 and June 2015 equity raises by the Company, will likely limit the annual use of these net operating loss carryforwards.

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.

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The Company does not have any unrecognized tax benefits 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 earliest open tax year subject to examination is 2010.

*Note 17*

**Business Segments and Geographic Data:**

The Company organized its business into three 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 XTRAC procedures performed by dermatologists. The Dermatology Procedures Equipment segment generates revenues from the sale of equipment, such as lasers and lamp products. The Dermatology Imaging segment generates revenues from the sale and usage of MelaFind devices. Management reviews financial information presented on an operating segment basis for the purposes of making certain operating decisions and assessing financial performance. On June 22, 2015, the Company acquired the XTRAC and VTRAC businesses and has classified the revenues and expenses of this business to the two Dermatology Procedures segments. Accordingly, these revenues and operating expenses are included only for the period of June 23, 2015 through December 31, 2015. There are no corresponding revenues for the year ended December 31, 2014.

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.

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

	Year Ended December 31, 2015			
	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Dermatology Imaging	TOTAL
Revenues	\$ 14,616	\$ 3,591	\$ 288	\$ 18,495
Costs of revenues	4,680	1,989	7,050	13,719
Gross profit	9,936	1,602	(6,762)	4,776
<i>Gross profit %</i>	68.0%	44.6%	(2347.8%)	25.8%
Allocated operating expenses:				
Engineering and product development	676	104	1,249	2,029
Selling and marketing expenses	7,128	193	1,873	9,194
Unallocated operating expenses	-	-	-	10,028
	7,804	297	3,122	21,251
Income (loss) from operations	2,132	1,305	(9,884)	(16,475)
Interest expense, net	-	-	-	(10,200)
Change in fair value of warrant liability	-	-	-	1,814
Other income (expense), net	-	-	-	33
Income (loss) before income taxes	\$ 2,132	\$ 1,305	(\$ 9,884)	(\$ 24,828)

	Year Ended December 31, 2014			
	Dermatology Recurring Procedures	Dermatology Procedures Equipment	Dermatology Imaging	TOTAL
Revenues	\$ -	\$ -	\$ 915	\$ 915
Costs of revenues	-	-	4,935	4,935
Gross profit	-	-	(4,020)	(4,020)
<i>Gross profit %</i>	0.0%	0.0%	(439.3%)	(439.3%)
Allocated operating expenses:				
Engineering and product development	-	-	1,641	1,641
Selling and marketing expenses	-	-	3,140	3,140
Unallocated operating expenses	-	-	-	7,821
	-	-	4,781	12,602
Loss from operations	-	-	(8,801)	(16,622)
Interest expense, net	-	-	-	(2,372)
Change in fair value of warrant liability	-	-	-	8,103
Gain on sale of assets	-	-	-	16
Other income (expense), net	-	-	-	150
Registration rights liquidated damages	-	-	-	(3,420)
Loss before income taxes	\$ -	\$ -	(\$ 8,801)	(\$ 14,145)

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For the year ended December 31, 2015 and 2014 there were no material net revenues attributable to any individual foreign country. Net revenues by geographic area were, as follows:

	Years Ended December 31,	
	2015	2014
Domestic	\$14,724	\$ 340
Foreign	3,771	575
	\$18,495	\$ 915

As of December 31, 2015 and 2014, total assets by reportable segment were as follows:

	December 31,	
	2015	2014
Assets:		
Dermatology Recurring Treatments	\$ 40,420	\$ -
Dermatology Treatment Equipment	5,364	-
Dermatology Imaging	661	19,181
Other unallocated assets	4,927	889
Consolidated total	\$ 51,372	\$ 20,070

Long lived assets were 100% located in domestic markets for both of the years ended December 31, 2015 and 2014.

*Note 18*

**Related Parties:**

On June 22, 2015, the Company entered into a securities purchase agreement with the Purchasers, including certain funds managed by Sabby Management, LLC and Broadfin Capital LLC, in connection with a private placement. We sold \$10.0 million aggregate principal amount of Notes bearing interest at 9% per year, with a maturity date of the earlier of 30 days after the Company obtains stockholder approval of stock issuances under the Debentures and the Warrants or November 30, 2015. The Purchasers of the Notes were issued Warrants to purchase an aggregate of 3.0 million shares of common stock, having an exercise price of \$0.75 per share. We also issued \$32.5 million aggregate principal amount of Debentures that, subject to certain ownership limitations and stockholder approval conditions, will be convertible into 43,333,334 shares of common stock at an initial conversion price of \$0.75 per share. The Debentures bear interest at the rate of 2.25% per year, and, unless previously converted, will mature on the five-year anniversary of the date of issuance. Our obligations under the Debt Securities are secured by a first priority lien on all of our assets, except for a second lien on our intellectual property. As a condition of the new term note facility (See *Note 11, Long-term Debt* below) the Debentures from both the 2014 and 2015 financings were amended. The Debentures holders' first priority lien was subordinated to the new term note facility. Additionally, as a condition of the term note facility, the maturity date of both Debentures was extended to June 30, 2021. Effective upon the date the Stockholder Approval, on September 30, 2015, the Company repriced outstanding Warrants held by certain investors to reduce the exercise price to \$0.75 per share.

In connection with this financing, the Company also granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Debentures and the Warrants pursuant to the terms of the Registration Rights Agreement. In addition to the registration rights, the Selling Stockholders are entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, becoming effective and maintaining an effective registration statement covering the shares underlying the Debentures and the Warrants. The liquidated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquidated damages payable is equal to 2.0% of the aggregate purchase price paid by each Purchaser, provided, however, the maximum aggregate liquidated damages payable to a Purchaser shall be 12% of the aggregate subscription amount paid by such Purchaser pursuant to the Purchase Agreement. The liquidated damages shall accrue interest at a rate of 12% per annum (or such lesser maximum amount that is permitted to be paid by applicable law), accruing on a daily basis for each event until such event is cured.

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

The Registration Rights Agreement requires the Company to file one or more registration statements for all of the securities that may be issued upon conversion of the Debentures and exercise of the Warrants issued to the Purchasers. Pursuant to the applicable transaction documents, however, certain Purchasers may not exercise their conversion/exercise rights for that number of shares of common stock which, together with all other shares owned by that Purchaser and its affiliates would result in more than 9.99% of our issued and outstanding shares of common stock calculated on the basis of the then outstanding shares.

On November 4, 2015, the Company entered into consulting agreements with two of its directors, Jeffrey F. O'Donnell, Sr. and Samuel E. Navarro, the terms of which are the same. Under the terms of their respective agreements, each director agrees provide strategic support, advice and guidance to the Company and its management team in connection with the integration and operation of the expanded business, investor relations and internal and external business development activities. The consultant will make himself available to the Company's President and Chief Executive Officer and the management team on request at mutually convenient times and will report to the Board of Directors quarterly and otherwise when requested by the Board. The term of the agreement is from November 4, 2015 through June 30, 2016. The directors are each to be paid an up-front fee of \$40,000 for advice and services rendered prior to the date of the agreement, a retainer of \$10,000 per month, commencing November 10, 2015 and continuing on the tenth day of each month through June 10, 2016, and reimbursement of pre-approved, out-of-pocket expenses.

*Note 19*

**Significant Customer Concentration:**

For the year ended December 31, 2015, revenues from sales to the Company's international master distributor were \$3,085, or 16.7%, of total revenues for such period. At December 31, 2015, the accounts receivable balance from GlobalMed Technologies was \$533, or 13.1%, of total net accounts receivable. No other customer represented more than 10% of total company revenues for the years ended December 31, 2015 and 2014.

*Note 20*

**Subsequent Events:**

On January 22, 2016, the Company agreed to extend the expiration date of two outstanding Series B common stock warrants for six months. The two warrants, exercisable for an aggregate of 4,795,321 shares of Common Stock of the Company at an exercise price of \$0.75 per share, may be exercised by the respective holder at any time until July 24, 2016.

On January 29, 2016, the Company drew down the second tranche under the Credit Facility in the amount of \$1.5 million. The Company has, therefore, drawn down the total amount of the \$12.0 million available under the Credit Facility.

In connection with the drawdown of the second tranche under the Credit Facility, the Company issued to the lenders warrants to purchase an aggregate of 99,057 shares of the Company's common stock at an exercise price of \$1.06 per share, which equals the VWAP for the ten-day period prior to the January 29, 2016 closing date. The warrants are exercisable for five years from the date of issuance. The Warrants have not been registered under the Securities Act of 1933, as amended (the "Act"), pursuant to the exemption under Section 4(a)(2) of the Act.

On February 24, 2016, investors converted debentures amounting to \$15 into 20,000 shares of common stock. On March 3, 2016, investors converted debentures amounting to \$38 into 50,000 shares of common stock. Additionally, on March 11, 2016, investors converted debentures amounting to \$113 into 150,000 shares of common stock. See *Note 10, Convertible Debentures*.