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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 3, 2015

MELA SCIENCES, INC.
(Exact Name of Registrant Specified in Charter)

Delaware	**000-51481**	**13-3986004**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

100 Lakeside Drive, Suite 100, Horsham, Pennsylvania	**19044**
(Address of Principal Executive Offices)	(Zip Code)

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

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

The Company

Overview

We are 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 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 MELA into a leading medical dermatology company. We further believe that the cash flow generated by these businesses will be sufficient to finance our operations, including the continuing commercialization of the MelaFind® system, or MelaFind. The successful commercialization of MelaFind is dependent on 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® Excimer Lasers

XTRAC is an ultraviolet (UV) light, excimer laser technology. It received an FDA clearance in 2000 and has since become a widely recognized treatment among dermatologists for psoriasis and other skin diseases for which there are no cures. Excimer lasers emit very concentrated UV light and are used in ophthalmology and dermatology practices. Our XTRAC brand lasers deliver ultra narrow-band ultraviolet B (UVB) light to affected areas of the skin in order to treat an array of skin conditions, including psoriasis and vitiligo, which combined affect up to 10.5 million people in the U.S. and 190 million people worldwide.

Present in natural sunlight, UVB is an accepted psoriasis treatment that penetrates the skin to slow the growth of damaged skin cells. UVB therapy occurs as patients expose their affected skin to a UVB light source for a set length of time on a regular schedule. In our XTRAC system, we have refined the delivery of optimum amounts of UVB directly to skin lesions. The XTRAC lasers emit a high-intensity beam of ultra-narrow-band UVB, which many studies prove can clear psoriasis faster and produce longer remissions than broad-band UVB. In comparison to broad-band UVB, narrow-band UVB also require fewer treatments to produce the desired effect.

We market two excimer laser brands: the XTRAC Ultra Plus and the XTRAC Velocity. The Velocity is a more advanced and faster machine, allowing clinicians to treat a greater surface area in a shorter period of time, and as a result is able to treat all disease levels (mild, moderate and severe).

The XTRAC is marketed in the U.S. under a recurring revenue model; in which we generate incremental income on a per-use basis from the systems placed in physicians' offices. We estimate that there are roughly 1,000 XTRAC lasers in use in the U.S., of which 640 systems were, as of March 31, 2015, included in the recurring revenue model. In markets outside the U.S., the XTRAC laser is marketed primarily as a capital sale through a master international distributor to distributors in several key international markets. leaving considerable opportunity for growth. The target U.S. audience for XTRAC lasers comprises approximately 3,500 dermatologists who perform disease management.

We believe that XTRAC treatment leads to remission of patients' psoriasis in an average of 8 to 12 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. Insurance Reimbursement to physicians averages approximately $175 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 Lasers are FDA-cleared, fully reimbursable, National Psoriasis Foundation-endorsed phototherapy treatments for psoriasis.
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. In the treatment of vitiligo, the XTRAC UVB light functions to reignite 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.

Traditionally, vitiligo treatments have been considered cosmetic procedures, and as such, were not reimbursed by insurance companies. However, over the past several years, there has been a significant increase in insurance coverage for these procedures, although it still lags behind the widespread reimbursement for psoriasis.

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 dermatologist 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 with one of our dermatologist customers for an evaluation and treatment regimen.

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. We envision MelaFind ultimately becoming an integral part of the standard of care in melanoma detection. To achieve this objective, we are executing the following strategies:

- *Establish MelaFind in key institutions.* We have placed the MelaFind System with many of the most prestigious pigmented skin lesion experts and institutions in the U.S. and Germany. Many of these recognized experts conduct clinical trials that support publications and presentations at conferences.

- *Focus on dermatologists who treat high risk patients.* The profile of patients at high risk for melanoma are patients with fair skin, freckles and light hair, with a previous or family history of melanoma and people who have been exposed to ultraviolet A (long-wave) and ultraviolet B (short-wave) rays from tanning beds and sun bathing.

- *Pursue reimbursement.* 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 are effective January 1, 2016. The codes will provide the initial basis for pursuing third party and CMS insurance coverage for MelaFind.

- *Continue to improve the MelaFind device.* Based on feedback from physicians as well as internally generated initiatives, we make continual efforts to improve reliability and customer experience of the MelaFind system.

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. We anticipate that the PAS will require significant funding to reach its conclusion, currently anticipated in 2018.

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.

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 are 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 laser 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. Potential competition for us in this category could come from Biogen Idec Inc. (BIIB-NASDAQ), Centocor, Inc. (a Johnson & Johnson company), Abbott Laboratories (ABT-NYSE), and others which are engaged in R&D and commercialization of treatments in these areas. In some cases, these companies have already received FDA approval for products or commenced clinical trials for such treatments.

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.

We also compete with other imaging modalities, including molecular imaging in which tagged antibodies search for cancer cell antigens, and with molecular and genetic screening tests. Molecular-based approaches are also being investigated; for example one company of which we are aware is exploring Messenger RNA analysis of surface cells. Its core technologies are 1) a patented, non-invasive technique that uses an adhesive to collect cells from the upper layer of the skin, and 2) multi-gene biomarkers that are generated using microarray analysis. The ribonucleic acid ("RNA") from these cells is then isolated, amplified, and analyzed using molecular biology tools.

The broad market for precision optical imaging devices used for medical diagnosis is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We could potentially be subject to competition from major optical imaging companies, such as Raytheon Corporation, General Electric Co., Siemens AG, Bayer AG, Olympus Corporation, Carl Zeiss AG Deutschland and others, each of which manufactures and markets precision optical imaging products for the medical market and could decide to develop or acquire a product to compete with MelaFind.

Manufacturing

We manufacture our excimer laser products and our excimer lamp product at our 19,900 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 have employed contract manufacturers to build components of our MelaFind system. 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. We have discontinued the use of our current cart and monitor component and plan to implement off the shelf units in a future version.

Research and Development Efforts

Our research and development team, including engineers, consists of approximately nine employees. We conduct research and development activities at our facilities located in Carlsbad, California and Irvington, NY. 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.

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 June 30, 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 seek licenses from third parties for technology that can broaden our product and service offerings. For example, we secured a license from the Mount Sinai School of Medicine, New York, New York, which granted us exclusive rights to a patent directed to the use of excimer lasers in the treatment of vitiligo.

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.

With respect to MelaFind, we have developed trade secret calibration methods, classifier programs, and search engines. These programs have been developed over many years and incorporate decades of experience in optical computer vision. In addition, our proprietary MelaFind database of over 10,000 lesions has been compiled over many years and would be difficult to replicate.

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 and MelaFind systems and other products currently under development by us and govern the manufacture and labeling of the cosmetic products. 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 system 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 laser or electrosurgical cutting devices 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.

To date, we have only been 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.

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 of 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 beginning in February 2010 and to investigate any violation that involves willful neglect which carries mandatory penalties beginning in February 2011. 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 June 30, 2015, 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 $156.25 per treatment;

- 96921 – designated for: the total area 250 to 500 square centimeters. CMS assigned a 2015 national payment of approximately $172.70 per treatment; and

- 96922 – designated for: the total area over 500 square centimeters. CMS assigned a 2015 national payment of approximately $238.84 per treatment.

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

Employees

As of June 30, 2015, we had 119 employees in the U.S., of whom 10 were engaged in research and development, 20 in operations (including clinical, regulatory affairs, document control and quality assurance) and 89 in marketing, sales and administrative activities.

Other

We were incorporated in the State of New York in 1989 under the name Electro-Optical Sciences, Inc. and subsequently reincorporated under the laws of the State of Delaware in 1997. In April 2010, we changed our name to MELA Sciences, Inc. Our executive offices are located at 100 Lakeside Drive, Suite 100, Horsham, PA 19044. Our telephone number is (215) 619-3200 and our Internet address is www.melasciences.com.

Risk Factors

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 three months ended March 31, 2015 was approximately $7.3 million, and as of March 31, 2015, we had an accumulated deficit of approximately $189.6 million. 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. Our profitability will be negatively impacted by expenses related to the Acquisition financing. Our losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

The report of our independent auditors dated March 30, 2015, on our financial statements for the period ended December 31, 2014, included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Our auditors' doubts are based on our inability to establish an ongoing source of revenue sufficient to cover our operating costs and recurring losses from operations. Our ability to continue as a going concern will be determined by our ability to generate sufficient cash flow to sustain our operations and/or raise additional capital in the form of debt or equity financing. We believe the acquisition of the XTRAC and VTRAC businesses in June 2015 will enable us to generate sufficient cash flow so as to allow us to operate without need for additional external financing for the foreseeable future. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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 no 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:

- Ÿ unforeseen difficulties in integrating operations, technologies, services, accounting and personnel;
- Ÿ diversion of financial and management resources from existing operations;
- Ÿ unforeseen difficulties related to entering geographic regions where we do not have prior experience;
- Ÿ risks relating to obtaining sufficient equity or debt financing;
- Ÿ risks relating to obtaining sufficient equity or debt financing;
- Ÿ 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 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 commercial distribution for our XTRAC system and certain of our other products. Even if adequate financing is available and such products are ready for market, the Company 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 yield 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 its psoriasis treatment and, based on these studies, we have gained FDA clearance, appropriate Current Procedural Terminology, or CPT, reimbursement codes for treatment and suitable reimbursement rates for those codes, from the Centers for Medicare & Medicaid Services, or 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.

Beginning in early 2010, Dr. John Y.M. Koo, the director of the Psoriasis Treatment Center at the University of California San Francisco Medical Center, initiated a clinical study to demonstrate the effectiveness of the XTRAC Velocity in combination with the drugs Clobex® and Vectical®, both from Galderma, for patients with severe psoriasis. This study may or may not result in demonstrating the effectiveness of those products in combination, or the treatment protocol and the treatment protocol may or may not gain FDA clearance. Even if the treatment protocol is successful and gains FDA clearance, limitation of supply of one or both drugs by Galderma, and lack of viable substitutes therefore, may adversely impact use of or compliance with the treatment protocol as a therapy for treatment of psoriasis. Further, the FDA limits claimed indications for use to those found in the "Instructions for Use Statement" in a device's 510(k) clearance letter. The FDA may view certain of the Company's claims of treatment as outside the scope of the device's cleared indications for use.

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 Patient Protection and Affordable Care Act of 2010 (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 June 30, 2015, 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. Based on these reports and estimates, we are continuing the implementation of a roll-out strategy under revised user models for the XTRAC system in the U.S. in selected areas of the country where reimbursement is widely available. The success of the roll-out depends on increasing physician and patient awareness and demand for the treatment. 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 U.S. Department of Health and Human Services ("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-sale 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:

- Ÿ to hire, as needed, a sufficient number of qualified sales and marketing personnel with the aptitude, skills and understanding to market our products;
- Ÿ 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;
- Ÿ 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
- Ÿ 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 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 maintains 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 or our products including recall, and could have a material adverse effect upon our business, financial condition and results of operations.

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

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; 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, money 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. 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, 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 its results of operations or its ability to conduct our business. In addition, the adoption of new regulations or changes in the interpretations of existing regulations may result in significant compliance costs or discontinuation of product sales and may impair the marketing of our products, resulting in significant loss of net sales. Our failure to comply with federal or state regulations, or with regulations in foreign markets that cover our product claims and advertising, including direct claims and advertising by us, may result in enforcement actions and imposition of penalties or otherwise harm the distribution and sale of its products. Further, our businesses are subject to laws governing our accounting, tax and import and export activities. Failure to comply with these requirements could result in legal and/or financial consequences that might adversely affect our sales and profitability. Each medical device that we wish to market in the U.S. must first receive either 510(k) clearance or premarket approval, or PMA, from the FDA unless an exemption applies. Either process can be lengthy and expensive. The FDA's 510(k) clearance process may take from three to twelve months, or longer, and may or may not require human clinical data. The PMA process is much more costly and lengthy. It may take from eleven months to three years, or even longer, and will likely require significant supporting human clinical data. Delays in obtaining regulatory clearance or approval could adversely affect our revenues and profitability. Although we have obtained 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.

The Company's 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 premarket approval (PMA). In general, obtaining premarket approval 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.

The Company 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 the Company has such clearance and/or approvals for all of its 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 Company's 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 after August 1, 2013. 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 the Company.

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 Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010 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 beginning in January 2013, 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 the Company 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, the Company’s 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 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 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 MelaFind 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 the Company is unable to fully comply with such laws.

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

- the federal healthcare programs' Anti-Kickback Law, 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 the Company to the extent that the Company's 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

- Ÿ 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.

Recently, 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 the Company's operations or arrangements are found to be in violation of any of the laws described above or any other governmental regulations that apply to the Company, the Company 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 the Company's operations could adversely affect its ability to operate its business and its 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 the Company for violation of these laws, even if the Company successfully defends against that action and the underlying alleged violations, could cause the Company to incur significant legal expenses and divert its management's attention from the operation of its business. If the physicians or other providers or entities with whom the Company does business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on the Company's 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.

The Company and some of its 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. The Company and its manufacturers and suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if the Company markets its products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. The Company's 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 the Company's 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 the Company is in substantial compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. The Company is 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.

Recently, the medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If the Company's 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 the Company 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 ours 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 Company medical devices, that the Company 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 the Company to comply with statutes and regulations administered by the FDA and other regulatory bodies, discovery of previously unknown problems with its 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:

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

If any of these actions were to occur, it would harm the Company's reputation and adversely affect its 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 the Company or one of its 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 the Company determines 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 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 and will incur substantial costs related to the Acquisition and the related financing. These costs include fees for attorneys, accountants, filing fees and other costs. We estimate that we will incur, 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. If the total costs of the Acquisition, the related financing and the integration of operations exceed our estimates, our financial results could be adversely affected.

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 obtain insurance reimbursement and 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. The integration of the new business will be complex, time consuming and expensive, and could disrupt our business. We will need to overcome significant integration and allocation of resources challenges in a timely and efficient manner in order to realize any benefits from the Acquisition and have a successful integration of the operations and personnel. In addition, we will incur costs, which are not reasonably estimable, in the near term, associated with integrating the operations and management of the acquired business. We may incur additional material charges in subsequent quarters to reflect additional costs associated with the Acquisition and the related financing. 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.

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:

- Ÿ incorporating and rationalizing duplicative administrative support functions, including the transition of our finance and accounting activities to our acquired team in Horsham, PA;
- Ÿ assessing synergistic approaches to manufacturing, sales, distribution and marketing functions in order to optimize the inherent efficiencies of the acquisition across the entire business;
- Ÿ integrating the newly acquired businesses and personnel into a uniform financial reporting system, including ensuring internal controls and procedures are expanded to include all necessary reporting pathways;
- Ÿ 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
- Ÿ 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 acquired business may divert management's attention away from other operations.

Successful integration of the operations, products and personnel may place a significant burden on our management and internal resources. The diversion of the attention of management from current programs to 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. In addition, we may not be able to retain employees for the duration of the integration process or beyond. The failure to retain employees could result in higher operating expenses, disrupt our management and have a materially adverse effect on our financial condition, results of operations and cash flow. We expect to incur significant costs integrating our operations, products and personnel. These costs may include costs for:

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

In addition, other costs associated with the integration of the acquired business can be substantial. To the extent that we incur integration costs that were not anticipated, these unexpected costs could adversely impact our liquidity or force us to borrow or raise additional funds, further diverting management's attention from our operations and potentially further diluting our stockholders.

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 and the anticipated sales of MelaFind, once insurance reimbursement becomes effective. 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.

If the combined company does 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:

- Ÿ Sell or license some of our technologies that we would not otherwise sell or license if we were in a stronger financial position;
- Ÿ 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
- Ÿ 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.

Risks Relating to the 2015 Financing

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

The Debentures and the Notes 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. Our obligations under the Notes and Debentures are secured by a first priority lien on all of our assets, except for a second lien on our intellectual property. 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 and the Notes could require us to redeem such Debentures and Notes at a premium.

The Debentures and the Notes provide that, upon the occurrence of an "Event of Default," the interest rate on the Debentures and the Notes increases to 12%. Events of Default under the Debentures and the Notes 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 or the Notes; (3) certain events of bankruptcy or insolvency of our company; (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; and (5) our failure to satisfy the Stockholder Approval Requirement by November 30, 2015. In addition, upon an Event of Default, the Debentures and the Notes 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 and Notes, 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 and the Notes. 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 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. 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.

We have identified a material weakness in our internal control over financial reporting. If we fail to develop or maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

During the preparation of our consolidated financial statements for the year ended December 31, 2014, we and our independent registered public accounting firm identified deficiencies in our internal control over financial reporting, as defined in the standards established by the Public Company Accounting Oversight Board. See "Report of Management on Internal Control over Financial Reporting" in our Form 10-K filed with the SEC on March 31, 2015. Management determined the control deficiencies constitute a material weakness in our internal control over financial reporting.

Since December 31, 2014, as stated in "Report of Management on Internal Control over Financial Reporting," management has taken steps to remediate the material weakness cited at December 31, 2014. We cannot assure you that the measures we have taken will be effective in mitigating or preventing significant deficiencies or material weaknesses in our internal control over financial reporting in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses or cause us to fail to meet our periodic reporting obligations. The existence of a material weakness could result in errors in our financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in the trading price of our 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:

- Ÿ failure of any of our products to achieve or continue to have commercial success;
- Ÿ the timing of regulatory approval for our future products;
- Ÿ results of our research and development efforts and our clinical trials;
- Ÿ the announcement of new products or product enhancements by us or our competitors;
- Ÿ regulatory developments in the U.S. and foreign countries;
- Ÿ our ability to manufacture our products to commercial standards;
- Ÿ developments concerning our clinical collaborators, suppliers or marketing partners;
- Ÿ changes in financial estimates or recommendations by securities analysts;
- Ÿ public concern over our products;

- Ÿ developments or disputes concerning patents or other intellectual property rights;
- Ÿ product liability claims and litigation against us or our competitors;
- Ÿ the departure of key personnel;
- Ÿ the strength of our balance sheet;
- Ÿ variations in our financial results or those of companies that are perceived to be similar to us;
- Ÿ changes in the structure of third-party reimbursement in the U.S. and other countries;
- Ÿ changes in accounting principles or practices;
- Ÿ general economic, industry and market conditions; and
- Ÿ 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:

- Ÿ limit who may call a special meeting of stockholders;
- Ÿ 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;
- Ÿ do not permit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;
- Ÿ prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- Ÿ 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.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MELA SCIENCES, INC.

By: /s/ Robert W. Cook

Robert W. Cook

Chief Financial Officer

Date: August 3, 2015