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

Form 10-K

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

For the fiscal year ended December 31, 2014

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

For the transition period from _____ to _____

Commission file number 000-51481

MELA SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**13-3986004**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

50 South Buckhout Street, Suite 1
Irvington, New York 10533
(Address, including zip code, of registrant's principal executive offices)

(914) 591-3783
Registrant's telephone number, including area code:
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common stock, $0.001 par value	**The NASDAQ Stock Market LLC**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	x

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

The aggregate market value of the 5,170,303 shares of common stock held by non-affiliates of the registrant as of June 30, 2014 was $16,544,970 based on the last reported sale price of $3.20 per share on the Nasdaq Capital Market on June 30, 2014. (For this computation, the registrant excluded the market value of all the shares of its common stock held by Directors and Officers of the registrant holding approximately 0.8% of the registrant's outstanding shares; such exclusion shall not be deemed to constitute an admission that any such person is an "affiliate" of the registrant. The number of shares outstanding of the registrant's common stock as of March 30, 2015 was 7,525,146 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2015 Annual Meeting of Stockholders, which is to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K.

MELA SCIENCES, INC.

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This Annual Report on Form 10-K, including the sections labeled Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that you should read in conjunction with the financial statements and notes to financial statements that we have included elsewhere in this report. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. We generally identify these statements by words or phrases that contain words such as "believe," "anticipate," "assuming," "expect," "intend," "plan," "will," "may," "should," "estimate," "predict," "potential," "continue," "contemplate", or the negative of such terms or other similar expressions. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements, and you should not place undue reliance on these statements. Factors that might cause such a difference include those discussed below under the section "Risk Factors," as well as those discussed elsewhere in this Annual Report on Form 10-K. We disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the period covered by this report or otherwise.

Item 1. *Business*

Overview

We are a medical device company dedicated to designing and developing innovative software-driven technology for the early detection of skin cancer. We are focused on the commercialization of our flagship product, the MelaFind® System, or MelaFind, as well as the further design and development of this technology. MelaFind is a non-invasive, point-of-care (i.e. in the doctor's office) instrument to aid in the detection of melanoma. The System features a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated algorithms, "trained" by our proprietary database of melanomas and benign lesions. This result provides information to assist in the management of the patient's disease, including information useful in the dermatologist's decision on whether to biopsy the lesion.

MelaFind's components include:

- a *hand-held imager*, which employs high precision optics and multi-spectral illumination (multiple wavelengths of light);
- our *proprietary database* of pigmented skin lesions, believed to be the largest prospective database to date in the U.S.; and
- our *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions.

In November 2011, we received a Pre-Market Approval, or PMA, from the U.S. Food and Drug Administration ("FDA") for MelaFind, having already received in September 2011 Conformité Européenne ("CE") Mark approval. On March 7, 2012, we installed the first commercial MelaFind System. We initially marketed the MelaFind System to dermatologists through a lease program in which users paid an upfront placement fee and periodic fees for use. In 2013, we added the capital sale of the MelaFind system to our marketing approach. Revenues were $0.5 million and $0.3 million in 2013 and 2012, respectively, and did not meet our expectations. As a result we implemented a significant cost reduction program in 2013 that affected all areas of our business, and which continued throughout 2014. We undertook several steps that we believe may significantly improve MelaFind's commercial acceptance: 1) we elected to change our business model from solely a rental-based model to include a capital sales option as well; 2) we refocused our marketing efforts on medical dermatology, and particularly those dermatologists who treat patients at high risk for melanoma; and 3) we began a process aimed at ultimately obtaining a coverage determination from the Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers Medicare, in order to obtain reimbursement by Medicare and ultimately by private insurers for the use of MelaFind. During 2014 we made progress in each of these areas, although we anticipate that it will require several years of continued effort before the success of this strategy can be assessed. We anticipate that the insurance reimbursement process could take several years to complete.

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 becoming an integral part of the standard of care in melanoma detection.

The 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 United States. 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 United States was estimated at $2.36 billion (in 2010 dollars) based on a study sponsored by the National Cancer Institute.

Melanoma can be fatal if left untreated. If diagnosed and removed early in its evolution, when confined to the outermost skin layer and deemed to be *in situ*, the survival rate is almost 100%. Invasive melanomas that are thin and extend into the uppermost regions of the second skin layer still have excellent cure rates (greater than 90%). However, once the cancer advances into the deeper layers of skin, the risk of metastasis (spreading to other parts of the body) increases. Metastasis can occur when the cancer cells enter into lymphatic channels and newly formed blood vessels, potentially resulting in significant morbidity (illness) and mortality. Once the cancer has advanced and metastasized to other parts of the body, it becomes very difficult to treat. At this advanced stage, the five-year survival rate is approximately 15% to 20%. Survival rates for those with advanced melanoma have not significantly improved over the past three decades.

Melanoma is currently the fastest growing cancer and the subject of significant attention in the medical community. The incidence rate of melanoma has doubled since 1973, and is one of only three cancers with increasing rates. According to a study from the Mayo Clinic, the incidence of melanoma increased eightfold among women under 40 and fourfold among men under 40 from 1970 to 2009. Unlike many other common cancers, melanoma has a wide age distribution. In fact, it is one of the more common cancers in people younger than 30, the most common cancer in adults aged 25 to 29 and the leading cause of cancer death in women ages 25 to 30 and second only to breast cancer in women ages 30 to 34.

Our Strategy

We envision MelaFind 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.

- *Increase the number of abstracts, posters and clinical presentations at dermatology conferences.* During 2014, we presented 6 unique abstracts and posters. Additionally, we conducted 3 clinical advisory sessions to obtain critical data/information for further development of MelaFind and observed five reader studies designed to assess the impact of the MelaFind information on a dermatologist's decision to biopsy suspicious pigmented skin lesions.

- *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.* An application was submitted in July 2014 to obtain Current Procedural Terminology (CPT) codes. On March 9, 2015, the February 2015 CPT® Editorial Summary of Panel Actions was posted to the website of the American Medical Association ("AMA"). The CPT Editorial Panel accepted the addition of Category III codes 039XX1T and 039XX2T to report multi-spectral digital skin lesion analysis of atypical cutaneous lesions, which applies to our MelaFind System. Barring any further action by the Panel, we expect that these codes will be posted to the AMA CPT website by July 1, 2015 with an effective date of January 1, 2016 and 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.

- *Focus selling efforts in key areas of the U.S. and Germany.* Our team of sales representatives is focused on targeted areas of the U.S. where key institutions are located. Our international sales efforts are focused on Germany, which has a large population of patients at risk for melanoma and whose government advocates for early detection of melanoma. Private insurance is available in Germany for the use of the MelaFind system by physicians. We will continue to evaluate new markets both domestically and internationally as resources allow.

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.

Our proprietary database of pigmented skin lesions, which includes *in vivo* MelaFind data and corresponding histological results of over 10,000 biopsied skin lesions from over 7,000 patients, which we believe to be the largest such database in the U.S. and a substantial barrier to competition.

Our lesion classifiers are sophisticated mathematical algorithms. The "brain" of the MelaFind system, the lesion classifier distinguishes melanoma from non-melanoma using the lesion features extracted and measured by the hand-held imager. The mathematical formulas and algorithms used by the lesion classifiers are devised and optimized through the process of "classifier training" using lesions from our proprietary database. Lesion classifier development and training is an iterative process involving: (1) selection of the lesion features that provide for optimal lesion discrimination; and (2) optimization of the mathematical formulas to differentiate benign lesions from melanoma.

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 that MelaFind will detect all melanomas in the training data set with the highest possible specificity.

Reliable functioning of the MelaFind system is critical to its utility and success in the marketplace. Automated self-calibration tests are performed by the hand-held device to ensure proper functionality.

History of MelaFind

MelaFind Pivotal Clinical Trial

The MelaFind system PMA application was submitted to the FDA in June 2009. A pivotal clinical trial was conducted at seven centers across the U.S. and included 1,831 pigmented skin lesions from 1,383 patients. A binding Protocol Agreement with the FDA stipulated the sensitivity and specificity endpoints that were used to determine the safety and effectiveness of MelaFind. MelaFind detected 112 of 114 (98% measured sensitivity; lower confidence bound of 95%) melanomas that were eligible and evaluable for primary sensitivity endpoint analysis, and 125 of 127 (98% measured sensitivity; lower confidence bound greater than 95%) melanomas overall. Importantly, MelaFind detected 172/175 melanomas and "high grade lesions" (98% sensitivity; lower confidence bound greater than 95%). The Protocol Agreement called for sensitivity endpoints of at least 95% at a 95% lower confidence bound (a lower confidence bound of greater than 95% indicates that if the study were repeated, there would be less than a 5% chance that the sensitivity would be below 95%). MelaFind's measured specificity (9.5%), the ability to accurately rule out disease, was significantly superior to that of the study dermatologists (3.7%), who are skin cancer experts (p= 0.022). The Protocol Agreement called for MelaFind to be more specific than the study dermatologists at a p-value of less than 0.05 (a p-value of less than 0.05 indicates a less than 5% probability that the observed difference was due to chance).

Hardware and Software History

Askion GmbH, located in Germany, which specializes in precision optics, supplied the prototype and pre-production MelaFind hand-held assemblies used in our pivotal clinical trials. They continue to supply production hand-held assemblies for commercial sale. Askion also supports our R&D and design engineering activities. Nexcore Technologies, Inc, located in Waldwick, NJ, provides engineering support of the MelaFind cart assemblies.

We have obtained Underwriters' Laboratories ("UL") certification as related to environmental and product safety and Certification Bodies' Scheme ("CB") test certification for MelaFind. We have also achieved ISO 13485 certification by its registrar, BSI, for the design and development of medical devices.

All software has been, and continues to be, developed by our R&D/Product Development Group at its facility located in Irvington, NY.

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. Under the terms of the agreement, we are required to submit to the FDA progress reports on the PAS every six months during the first two years and annually thereafter. The first progress report was submitted to the FDA in February 2013 and the most recent report was submitted in February 2015. 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. The PAS is currently enrolling patients and is listed as "progress adequate" with the FDA.

Our Reimbursement Strategy

On March 9, 2015, the February 2015 CPT® Editorial Summary of Panel Actions was posted to the website of the AMA. The CPT Editorial Panel accepted the addition of Category III codes 039XX1T and 039XX2T to report multi-spectral digital skin lesion analysis of atypical cutaneous lesions, which applies to our MelaFind System. Barring any further action by the Panel, we expect that these codes will be posted to the AMA CPT website by July 1, 2015 with an effective date of January 1, 2016 and will provide the basis for pursuing third party and CMS insurance coverage for MelaFind. We expect to commence efforts in 2016 to obtain positive coverage decisions from private payers, managed care organizations, Medicaid agencies, and state Medicare administrative contractors upon the establishment of the CPT codes announced on March 9, 2015.

One of the keys to securing reimbursement is the desire of physicians to use a new technology in order to enhance their diagnostic acumen and improve the standard of care. We believe that MelaFind represents an improvement in the standard of care, and its adoption by physicians and reimbursement by payers depends on medical and scientific evidence published in peer-reviewed journals and presentations at scientific and medical meetings. We have executed a publication strategy and provided information for continuing medical education efforts in order to communicate the potential of MelaFind to improve patient care. In addition to the PAS, we also design and implement trials in order to evaluate MelaFind in the clinical setting. These studies include research studies as well as reader studies to evaluate the impact of MelaFind on a dermatologist's decision to biopsy a suspicious pigmented skin lesion. We expect that the results of these studies will be published in peer-reviewed journals during 2015, be presented at scientific and medical meetings, and that these studies will help to demonstrate the potential of MelaFind to improve patient care.

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

A number of systems 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.

Confocal Microscopy—Confocal microscopy is an optical imaging technique used to increase optical resolution and contrast of a micrograph. It enables the reconstruction of three-dimensional structures from the obtained images. We are aware of one company that offers products which utilize confocal microscopy. Their product line is used for non-invasive visualization of skin structures at the cellular level. Furthermore, we believe that researchers at Vanderbilt University are developing a technology which produces a molecular fingerprint of the underlying tissue to indicate the presence or absence of disease.

Spectrophotometric Intercutaneous Analysis – Spectrophotometric intercutaneous analysis is an analysis of skin structures through measurement of how they absorb light of different wavelengths. This technique visualizes collagen, blood, and pigment. We are aware of one company that offers a product utilizing spectrophotometric intercutaneous analysis. This system integrates light and digital imaging to evaluate lesions in five distinct views. The software produces a rating "score" for scanned lesions.

Spectrophotometric (Color) Analysis—Spectrophotometric (color) analysis is the quantitative measurement of the reflection or transmission properties of a material as a function of wavelength. It deals with visible light, near-ultraviolet, and near-infrared and can measure intensity as a function of the light source wavelength. We are aware of one company that offers a product, currently available in Germany, which uses spectrophotometric (color) analysis. Its product uses NIR Raman Spectroscopy and autofluorescence spectroscopy to identify spectral changes associated with the biochemistry of skin cancer cells.

Newly Identified Imaging Approaches—We are aware of two companies that are developing technologies utilizing newly identified imaging approaches. The first is electrical impedance, which is an imaging technique where the image of the conductivity or permittivity of part of the body is inferred from surface electrical measurements. One company has developed this technology in Sweden for melanoma detection and is based on a technology that uses the varying electrical properties of human tissue to categorize the cell structures and thereby detect malignancies. The other company uses 'Optical Transfer Diagnosis' to detect anomalies in human tissue to support the diagnosis of melanomas. This technology measures how much light is absorbed in healthy versus diseased tissue to determine whether cancer is present via morphologic–physiologic mapping.

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 employ 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.

We contracted with Askion GmbH in Germany, our authorized EU Representative, and an ISO 13485 certified manufacturer, which specializes in precision optics to perform the system integration of the MelaFind hand-held imager with cart assemblies and operating system software to support MelaFind system sales in Europe. Askion provides product repair and warehousing services for the European market. In the U.S., we have also contracted with Nexcore Technology Inc., an ISO 13485 certified manufacturer of medical devices located in New Jersey, to assemble and provide MelaFind cart assemblies and to perform system integration, warehousing and repair activities.

Research and Development Efforts

We continually seek to refine and improve MelaFind's hardware and software. Some improvements may require prior FDA approval before they can be marketed, via a PMA supplement. Several improvements are currently in development, and we anticipate that some of these improvements will be incorporated into newer versions of the MelaFind system.

Intellectual Property

Our policy is to protect our intellectual property by obtaining U.S. and foreign patents to protect technology, inventions and improvements important to the development of our business. As of December 31, 2014, twenty-three issued U.S. patents are in force, and many of these patents have foreign counterparts issued and pending. Of those issued, eighteen U.S. patents, eight Australian patents and one Japanese patent relate to various aspects of MelaFind technology. Two of the U.S. patents are design patents, while all others are utility patents. One additional U.S. utility patent relating to MelaFind is currently pending. The currently pending foreign patent applications that relate to MelaFind include four in the European regional phase (with the European Patent Office), five are pending in Australia, and six in Canada. Also, we have obtained non-exclusive licenses from several of our suppliers for critical components of MelaFind. We have not granted any significant licenses with respect to our intellectual property other than licenses granted in connection with our DIFOTI product on which development was discontinued in 2005.

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

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.

FDA Regulation

MelaFind is regulated as a medical device and is subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and abroad. The Food, Drug, and Cosmetic Act ("FD&C Act") and other federal and state statutes and regulations govern the research, design, development, preclinical and clinical testing, manufacturing, safety, approval or clearance, labeling, packaging, storage, record keeping, servicing, promotion, import and export, and distribution of medical devices in the U.S.

Unless an exemption applies, each medical device we wish to commercially distribute in the U.S. will require prior pre-market notification, 510(k) clearance, or PMA approval from the FDA. The FDA classifies medical devices into one of three classes. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are subject to general controls such as labeling, pre-market notification, and adherence to the FDA's Quality System Regulation ("QSR"), which is a set of current good manufacturing practices ("cGMP") as put forth by the FDA as guidelines for the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation and servicing of finished devices. Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, as well as general controls. Devices are placed in Class III, which requires approval of a PMA application, if insufficient information exists to determine that the application of general controls or special controls are sufficient to provide reasonable assurance of safety and effectiveness, or they are life-sustaining, life-supporting or implantable devices, or the FDA deems these devices to be "not substantially equivalent" either to a previously 510(k) cleared device or to a "pre-amendment" Class III device in commercial distribution before May 28, 1976, for which PMA applications have not been required. The FDA classifies MelaFind as a Class III device, requiring PMA approval.

A PMA application must be supported by valid scientific evidence, which typically requires extensive data, including technical, pre-clinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. A PMA application must include, among other things, a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. A PMA application also must be accompanied by a user fee, unless exempt. For example, the FDA does not require the submission of a user fee for a small business' first PMA.

Clinical trials are almost always required to support a PMA application, and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an Investigational Device Exemption ("IDE") to the FDA. An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent form are approved by appropriate institutional review boards ("IRBs") at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators.

The clinical studies of MelaFind are considered by the FDA as Non-significant Risk ("NSR") studies. Consequently, the trials were conducted under the auspices of an abbreviated IDE. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent. As a condition of PMA approval, the FDA has mandated that we conduct a Post-Approval Study of MelaFind ("PAS"), evaluating the sensitivity and false positive rate of physicians after using MelaFind to their performance if MelaFind was not available. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

The withdrawal of previously received approvals or failure to comply with existing or future regulatory requirements would have a material adverse effect on our business, financial condition and results of operations.

After a device is approved or cleared and placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act that may present a risk to health.

The FDA enforces regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors. Thus, we must continue to spend time, money, and effort to maintain compliance.

Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may lead to possible sanctions, including warning letters, fines and civil penalties, unanticipated expenditures, delays in approving or refusal to approve our applications, including supplements, withdrawal of FDA approval, product recall or seizure, interruption of production, operating restrictions, injunctions, and criminal prosecution.

Our contract manufacturers are required to have current ISO 13485 certification status and manufacture our products in compliance with current Good Manufacturing Practices ("cGMP") as set forth in the FDA QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA enforces the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. We expect that our subcontractors' manufacturing facilities will be subject to domestic and international regulatory inspection and review. If the FDA believes any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down the manufacturing operations of our contract manufacturers, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business. We cannot assure you that we will be able to comply with all applicable FDA regulations.

Non-FDA Government Regulation

The advertising of the MelaFind system is subject to both FDA and Federal Trade Commission regulations in the U.S. In addition, the sale and marketing of MelaFind is subject to a complex system of federal and state laws and regulations intended to deter, detect, and respond to fraud and abuse in the healthcare system. These laws and regulations restrict and may prohibit pricing, discounting, commissions and other commercial practices that may be typical outside of the healthcare business. In particular, anti-kickback and self-referral laws and regulations will limit our flexibility in crafting promotional programs and other financial arrangements in connection with the sale of our products and related services, especially with respect to physicians seeking reimbursement through Medicare or Medicaid. These federal laws include, by way of example, the following:

- the anti-kickback statute prohibits certain business practices and relationships that might affect the provision and cost of healthcare services reimbursable under Medicare, Medicaid and other federal healthcare programs, 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, which prohibits referrals by physicians of Medicare or Medicaid patients to providers of a broad range of designated healthcare services in which the physicians or their immediate family members have ownership interests or with which they have certain other financial arrangements;

- 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 the U.S. Department of Health and Human Services ("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, and imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. These laws also impose an affirmative duty on those receiving Medicare or Medicaid funding to ensure that they do not employ or contract with persons excluded from the Medicare and other government programs.

Many states have adopted or are considering legislative proposals similar to the federal fraud and abuse laws, some of which extend beyond the Medicare and Medicaid programs to prohibit the payment or receipt of remuneration for the referral of patients and physician self-referrals regardless of whether the service was reimbursed by Medicare or Medicaid. Many states have also adopted or are considering legislative proposals to increase patient protections, such as limiting the use and disclosure of patient-specific health information. These state laws typically impose criminal and civil penalties similar to the federal laws.

In the ordinary course of their business, medical device manufacturers and suppliers have been and are subject regularly to inquiries, investigations and audits by federal and state agencies that oversee these laws and regulations. Federal and state legislation has increased funding for investigations and enforcement actions, which have increased dramatically over the past several years. This trend is expected to continue. Private enforcement of healthcare fraud also has 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. These whistleblower suits by private persons, known as *qui tam* relaters, may be filed by almost anyone, including physicians and their employees and patients, our employees, and even competitors. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), in addition to its privacy provisions, created a series of new healthcare-related crimes.

Environmental Regulation

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We and our investigators and vendors are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

International Regulation

The medical device regulatory process for international distribution is subject to government regulations that may vary by country from those having few or no regulations to those having pre-market controls and pre-market acceptance. In the EU, medical devices require CE Mark in order to be placed in the market. The CE Mark certifies that a product has met EU consumer safety, health and environmental requirements. CE marking requires meeting the conditions of the European Directive to which the medical device applies. The directives regulate the design, manufacture, clinical trials, labeling, and post-market surveillance reporting activities for medical devices.

We successfully achieved the ISO 13485 certification for the design and development of medical devices through our international registrar, BSI. In September 2011, after review and approval of the MelaFind technical file, we received CE Mark approval for MelaFind also through BSI.

Product Liability and Insurance

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if MelaFind causes, or merely appears to have caused, an injury. Claims may be made by patients, healthcare providers or others involved with MelaFind. We have both general liability insurance and product liability insurance for MelaFind, which is and will be subject to deductibles and coverage limitations. We have also obtained clinical trial liability insurance in the U.S. and in certain European countries where required by statute or clinical site policy. Our future product liability insurance needs may not be available to us in amounts or on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business.

Employees

As of December 31, 2014, we had 32 full-time and 2 part-time employees in the United States, of whom 4 were engaged in research and development, 13 in operations (including clinical, regulatory affairs, document control and quality assurance) and 17 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 50 South Buckhout Street, Suite 1, Irvington, New York 10533. Our telephone number is (914) 591-3783 and our Internet address is www.melasciences.com.

Our annual report on Form 10-K, quarterly reports on Forms 10-Q, current reports on Forms 8-K, and amendments to those reports are available, without charge, on our website www.melasciences.com as soon as reasonably practical after they are filed electronically with the Securities and Exchange Commission (the "SEC"). Copies are also available, without charge, from MELA Sciences, Inc., 50 South Buckhout Street, Suite 1, Irvington, New York, 10533, Attention: Secretary.

Item 1A. ***Risk Factors***

You should carefully consider the following risk factors, as well as the other information contained in this report. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the trading price of our common stock would likely decline.

Risks Relating to Our Business

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 the MelaFind system. Our net loss for the year ended December 31, 2014 was approximately $14.1 million and as of December 31, 2014, we had an accumulated deficit of approximately $182.3 million. We will continue to incur expenses in connection with our commercialization and development activities related to MelaFind. We expect to incur medical, marketing and sales expenses, plus additional contract manufacturing and inventory costs over the next several years which will require additional funding. We cannot determine at this time when we will generate any significant revenue. 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. 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:

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

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

We may be unable to continue commercialization and continue development of MelaFind enhancements or other products without additional funding.

As of December 31, 2014, we had approximately $11.4 million in cash and cash equivalents and cash used in operations for the year ended December 31, 2014 was approximately $17.7 million. Our total liabilities at December 31, 2014 were approximately $7.8 million. We expect to incur significant losses for the foreseeable future and may not achieve operating profits or positive cash flows from operations. Our ability to fund operations is not assured and will be impacted by market acceptance of MelaFind, cost cutting measures that are in place currently or may be put into place in the future and our ability to raise capital. We anticipate that long-term we will need to raise additional funds to broaden the commercialization and awareness of MelaFind, including implementing our refocused marketing strategy focusing on the key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma. The timing and amount of any additional funding we may require will be affected by the commercial success of our MelaFind product. The amount of funding we will need will depend on many factors, including:

- the cost of commercialization activities, including medical, marketing and sales expenses, contract manufacturing and inventory expenses and support of the current domestic direct sales force and conducting activities in Germany;
- the cost of our operations and our marketing strategy;
- sales of MelaFind units;
- the amount of direct payments we are able to obtain from physicians utilizing MelaFind;
- the costs of maintaining regulatory approval;
- reimbursement amounts for the use of MelaFind that physicians are able to obtain from Medicare and third party payers;
- the success of our research and development efforts in product creation and enhancement, and meeting competitive services and technologies;
- the schedule, costs and results of any clinical trials and studies, including the Post-Approval Study;
- the costs of maintaining inventory and other manufacturing expenses and write downs of obsolete inventory;
- our ability to establish and maintain any collaborative, licensing or other arrangements, and the terms and timing of any such arrangements;
- the costs involved in defending any patent infringement actions or other litigation claims brought against us by third parties; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other rights.

There can be no assurances that we will be able to raise additional financing in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. Any additional funding that we may obtain in the future could be dilutive to common stockholders and could provide new investors with rights and preferences senior to common stockholders. In the event that we are unable to achieve profitable operations and/or raise additional funds, we would need to further reduce current operations, expansion plans would be cancelled or ultimately we may need to terminate operations. Failure to fund our operations will have a material adverse effect on our business and our stock price.

MelaFind may not be widely accepted by the dermatological community.

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 us and MelaFind. The medical community is often skeptical of new companies and new technologies, thus, we may be unable to gain access to potential customers in order to demonstrate the operation and effectiveness of 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. Insufficient market acceptance of MelaFind would have a material adverse effect on our business, financial condition and results of operations.

MelaFind may not achieve general market acceptance at a level that will make us profitable.

Our future growth and profitability will depend, in large part, on the success of our marketing strategy to focus on the key dermatologists who treat many of the patients at high risk for melanoma and reaching out to key opinion leaders in the field, while continuing to provide clinical studies and evidence to support reimbursement for the use of MelaFind among physicians, government and third party payers, and regulators.

Physicians tend to be slow to change their diagnostic and medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third party reimbursement. Physicians may not begin to use MelaFind until there is long-term clinical evidence to convince them to alter their existing methods of diagnosing or evaluating clinically atypical lesions. We cannot predict the speed at which physicians may adopt the use of MelaFind.

The degree of market acceptance of MelaFind® will depend on a number of factors, including:

- perceived effectiveness of MelaFind;
- convenience and cost of use;
- availability and adequacy of third-party coverage or reimbursement;
- publicity concerning MelaFind or competitive products;
- potential advantages over alternative diagnostic methodologies;
- introduction and acceptance of competing products or technologies; and
- the extent and success of our sales, marketing and distribution efforts.

If MelaFind does not achieve an adequate level of acceptance by patients, physicians, healthcare payers and regulators, we may not generate significant product revenue and we may not become profitable.

We are required to conduct a Post-Approval Study of MelaFind. If the results from this study are negative or we fail to meet the requirements of this condition of approval, we may not be able to maintain the approval of MelaFind.

As a condition of approval of our PMA, we must conduct a PAS evaluating the sensitivity and false positive rate of physicians after using MelaFind to their performance if MelaFind was not available. Conducting this PAS is costly and time consuming.

We are required to submit to the FDA progress reports on this study every six months during the first two years and annually thereafter. The first progress report was submitted to the FDA in February 2013 and the most recent in February 2015. If the FDA has questions on the data provided in a progress report, or believes the data are incomplete or insufficient, the agency may request additional information, including through a deficiency letter. For example, on October 17, 2013, we received a letter from the FDA stating the information in our August 2013 progress report with respect to the PAS was inadequate to allow the agency to complete its review. The FDA requested additional information, particularly with respect to the study's enrollment rate. In November 2013, we responded to the FDA's letter, outlining an updated enrollment plan as well as a new enrollment schedule, and in January 2014 the FDA approved both the enrollment plan and the new enrollment schedule. In February 2014, a protocol revision request was sent to the FDA in an attempt to add clarity for study investigators. The protocol revisions were approved by the FDA on October 22, 2014. The PAS is currently enrolling patients and is listed as "progress adequate" with the FDA. The FDA may seek the advice of advisory panels of outside experts when considering the initiation or progress of post-approval studies. If we have not met the study milestones or timeline specified in the study protocol, we must provide a rationale to the FDA in our progress reports. If a change in the study milestones or timeline could significantly affect the outcome of the Post-Approval Study, we will need to submit that revision for the agency's review and approval. We will need to update MelaFind's labeling with the results from this study, including any positive or negative results.

We may be unable to complete our Post-Approval Study if, for example, we institute a recall of MelaFind from the market. The FDA can terminate our study if we have not fulfilled or cannot fulfill the Post-Approval Study condition of approval; for example, if MelaFind is not being sold because the device technology is obsolete, study questions are no longer relevant, we withdraw the PMA, or the study cannot answer the Post-Approval Study question. If the FDA determines the study cannot be completed as designed or because of study data inadequacies, but the study objectives remain important, the FDA may terminate the original study and discuss establishing a new post-approval study commitment and schedule. In appropriate circumstances, the FDA may order additional post-market surveillance.

The FDA may initiate withdrawal of approval of the PMA if the agency concludes we have not met the Post-Approval Study condition of approval and have not provided a valid scientific justification for doing so. The FDA also may withdraw the approval of the PMA (1) based on negative results from the Post-Approval Study that indicate the device is unsafe or ineffective under the approved labeling or (2) if we fail to conduct the study in accordance with the FDA's regulations, including those related to institutional review board and informed consent. If the PMA approval is withdrawn, we would be unable to continue marketing the device in the United States without violating the Federal Food, Drug, and Cosmetic Act. The sites involved in our Post-Approval Study and we as sponsor of the study can be inspected by the FDA at any time to assess compliance with the Post-Approval Study agreement, protocol adherence, human subject protection, and data integrity.

MelaFind may not be commercially viable if we fail to obtain an adequate level of reimbursement by Medicare, Medicaid and other third party payers.

The availability of medical insurance coverage and reimbursement for newly approved medical devices is uncertain. In the U.S., physicians and other healthcare providers performing biopsies for clinically atypical skin lesions are generally reimbursed for all or part of the cost of the diagnosis and biopsy by Medicare, Medicaid, or other third party payers. Commercial success of MelaFind and our financial condition will depend on whether third-party coverage and reimbursement are available for services involving MelaFind.

In the U.S., Medicare, Medicaid, health maintenance organizations and other third-party payers are increasingly attempting to contain healthcare costs by limiting both the scope of coverage and the level of reimbursement of new medical devices, and as a result, they may not cover or provide adequate payment for the use of MelaFind. In order to obtain satisfactory reimbursement arrangements, we may have to agree to a fee or sales price lower than the fee or sales price we might otherwise charge. Even if Medicare and other third-party payers decide to cover procedures involving our product, we cannot be certain that the reimbursement levels will be adequate. Accordingly, unless government and other third-party payers provide adequate coverage and reimbursement for our products, some physicians may be discouraged from using them, and our sales would suffer.

Medicare reimburses for medical devices in a variety of ways, depending on where and how the device is used. However, Medicare only provides reimbursement if the Centers for Medicare & Medicaid Services, the federal agency that administers Medicare ("CMS"), determines that the device should be covered and that the use of the device is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor, a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS through a national coverage determination. There are statutory provisions intended to facilitate coverage determinations for new technologies. Coverage presupposes that the device has been cleared or approved by the FDA and further, that the coverage will be no broader than the approved intended uses of the device as approved or cleared by the FDA, but coverage can be narrower. A coverage determination may be so limited that relatively few patients will qualify for a covered use of the device. Should a very narrow coverage determination be made for MelaFind®, it may undermine the commercial viability of MelaFind.

Germany is the only country in the world with a national skin screening program. Based on this program, public insurance (90% of the population) covers a visual examination only conducted by a General Practitioner or dermatologists — they do not yet cover imaging technologies/diagnostics devices. For coverage of imaging technologies/diagnostic devices, patients must be privately insured, have supplemental insurance or pay out-of-pocket. Private insurance (10% of the population) and/or supplemental insurance coverage reimbursement varies by policy, but ranges from $65 to $195 for imaging technologies. We cannot be certain that all private German insurers will reimburse the use of MelaFind or that the reimbursement will be adequate to support our business in Germany.

Obtaining a coverage determination by Medicare or Medicaid is a time-consuming, expensive and highly uncertain proposition.

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.

Even if MelaFind is approved for reimbursement by Medicare, Medicaid and/or other third party payers, we anticipate there will be significant pressures on pricing.

We expect to experience pricing pressures in connection with the commercialization of MelaFind due to efforts by private and government-funded payers to reduce or limit the growth of healthcare costs, the increasing influence of health maintenance organizations, and additional legislative proposals to reduce or limit increases in public funding for healthcare services. Private payers, including managed care payers, increasingly are demanding discounted fee structures and the assumption by healthcare providers of all or a portion of the financial risk. Efforts to impose greater discounts and more stringent cost controls upon healthcare providers by private and public payers are expected to continue. Payers frequently review their coverage policies for existing and new diagnostic tools and can, sometimes without advance notice, deny or change their coverage policies. Significant limits on the scope of services covered or on reimbursement rates and fees on those services that are covered could have a material adverse effect on our ability to successfully commercialize MelaFind and therefore, on our liquidity, margins and our business, financial condition, and results of operations.

We depend on clinical investigators and clinical sites and other third parties to manage our clinical trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

We have and will continue to rely on clinical investigators and clinical sites, some of which are private practices, and some of which are research, university or government affiliated, to enroll patients in any future clinical trials which we may conduct, as well as our FDA mandated post-approval studies. We have and will continue to rely on: pathologists and pathology laboratories; a contract research organization to assist in monitoring, collecting data, and ensuring FDA Good Clinical Practices ("GCP") are observed at our sites; a consultant biostatistician; and other third parties to manage trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites and other third parties devote to our clinical trials or studies. Our agreements with clinical investigators and clinical sites for clinical testing generally place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials or studies could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain are compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials or studies may be extended, delayed or terminated, and we may be unable to complete our studies or obtain regulatory approval for any other products which may be developed from our core technology. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or studies, or if the clinical sites fail to comply adequately with the clinical protocols, we will be unable to complete any such trials or studies, which could prevent us from obtaining regulatory approvals for the products being developed.

In addition to the foregoing, any future clinical trials may be delayed or halted for numerous other reasons, including, but not limited to, the following:

- the FDA, an Institutional Review Board ("IRB") or other regulatory authorities place our clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patient follow-up is not at the rate we expect;
- IRBs and third-party clinical investigators delay or reject our trial protocol;

- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical trials or facilities manufacturing our products, among other things, require us to undertake corrective action or suspend or terminate our clinical trials, or invalidate our clinical trials;
- changes in governmental regulations or administrative actions; and
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness.

Technological breakthroughs in the diagnosis or treatment of melanoma could render MelaFind obsolete.

The precision optical imaging field is subject to rapid technological change and product innovation. MelaFind is based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies such as confocal microscopy, an approach for non-invasive visualization of skin structures at the cellular level; and confocal Raman Micro-Spectroscopy which uses a reflective laser to produce a molecular fingerprint of the underlying tissue to indicate the presence or absence of disease. Other imaging modalities being developed include molecular imaging, in which tagged antibodies search for cancer cell antigens.

Also being developed is an electrical impedance technology for melanoma detection. The method is based on a technology that uses the varying electrical properties of human tissue to categorize the cell structures and thereby detect malignancies. Furthermore, several additional light based imaging approaches have recently been identified, including:

- a technology that measures how much light is absorbed in healthy versus diseased tissue to determine whether cancer is present;
- a satellite-based remote imaging technology for use in detecting skin changes which could indicate the presence of cancer;
- a scanner that provides real-time sub-surface images of tissue at far higher resolution than is possible with existing technologies such as ultrasound, CT or MRI, in 2D and 3D;
- a device that currently uses reflected visual light to analyze non-melanoma lesions;
- a device for non-invasive diagnosis of and screening for skin cancer; and
- a method for computer-aided analysis of photographs of skin lesions to detect the cancer which uses a traditional RGB (Red Green Blue) image as its computer source.

The commercial development, market acceptance and reimbursement approval of any of these new technologies could result in a technological breakthrough in the diagnosis and/or treatment of melanoma, which could render MelaFind less accepted or obsolete.

We operate in a highly competitive market, we may face competition from large, well-established medical device manufacturers with significant resources, and we may not be able to compete effectively.

While several companies including Verisante, Scibase and Caliber Imaging and Diagnostic, Inc. (formerly Lucid, Inc.) have technologies that may be used to assist the dermatologist, none of these companies' products have undergone the rigors of FDA PMA review and subsequent approval. Other products that enhance the visualization and analysis of potential melanomas are in use or are under development by: Welch Allyn, Inc.; Heine Optotechnik; 3Gen, LLC; Derma Medical Systems, Inc.; MedX Health; Biomips Engineering, Michelson Diagnostics, Riester, ViseoMed, AG and others. In addition, several companies have developed various dermatological apps for use with an Apple iPhone. The broader 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 will 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. These companies enjoy numerous competitive advantages, including:

- significantly greater name recognition;

- established relations with healthcare professionals, customers and third-party payers;
- established distribution networks;
- additional lines of products, and the ability to offer rebates, higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we may not be able to compete effectively against these companies or their products.

If we are unable to successfully implement our marketing strategy, our business may be harmed.

We have a limited sales organization, and have limited experience in the marketing and distribution of MelaFind or similar devices. To achieve commercial success for MelaFind, we must provide data to those operating in the dermatological industry to support their use of MelaFind, continue to conduct clinical studies, produce abstracts and publications and eventually achieve public and private insurance reimbursement for MelaFind. We believe that it is critically important to build brand and product awareness and confidence on the use and potential use of our product. We plan to focus on key thought leaders in key institutions to provide the market with up-to-date data on MelaFind and those dermatologists that treat high risk patients. We have established a small direct sales force to market MelaFind in the U.S. and Europe (initially in Germany), focused on introducing it to our intended market, including dermatologists who treat patients at high risk for melanoma and training their staffs in its use. We anticipate that we will need additional funds in order to fully implement our marketing strategy.

We are dependent upon the capability of contract manufacturers to produce our units, which can be out of our control.

We have limited experience in manufacturing MelaFind for commercial distribution and are using a contract manufacturer to produce our units. When we enter into contracts for the third-party manufacture of our devices, the quality of the devices will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Manufacturers often encounter difficulties in scaling up production of new products, including problems involving product yields, controlling and anticipating product costs, quality control and assurance, component supply, and shortages of qualified personnel. We cannot assure you that the third-party contract manufacturers with whom we have developed or are developing relationships will have or sustain the ability to produce the quantities of MelaFind needed for development or commercial sales at prices that allow MelaFind to compete successfully in the market.

Our manufacturing operations for MelaFind are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.

For manufacturing MelaFind, we rely on several vendors for critical components and materials such as: ON Semi, Carl Zeiss Jena GmbH (“Zeiss”), AB Electronics, AmeriCad and Canvys Electronics. Additionally, we are currently working with Askion in Germany for the provision of the hand-held components and tested MelaFind systems. We are utilizing Nexcore Technology Inc., an FDA regulated and ISO certified contract manufacturer of medical devices in New Jersey, to provide the assembled MelaFind carts and tested MelaFind systems.

There can be no assurance that these third parties will meet their obligations. Our contract suppliers may rely on sole-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to procure their raw material on time, failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- suppliers may make errors in manufacturing components that could negatively impact the effectiveness or safety of our products, or cause delays in shipment of our products;
- we may have difficulty locating and qualifying alternative suppliers for our sole-source suppliers;

- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;

- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

We have entered into an agreement with Askion to continue developmental engineering, production and testing of our hand-held component, and to also assemble and test the integrated finished MelaFind system, including the cart, for units to be sold within the European Union. Failure to maintain such an agreement with Askion on mutually acceptable terms would require us to find other contract manufacturing facilities.

MelaFind is complex and may contain undetected design defects and errors, which could have a material adverse impact on our business, financial condition and results of operations.

MelaFind is complex and may contain undetected design defects and errors when first introduced, or errors that may be introduced when enhancements are released. Such defects and errors may occur despite our testing, and may not be discovered until after our devices have been shipped to and used by our customers. The existence of these defects and errors could result in costly repairs, returns of devices, diversion of development resources and damage to our reputation in the marketplace. In addition, when we contract with third-party manufacturers for the production of our products, these manufacturers may inadvertently produce devices that vary from devices we have produced in unpredictable ways that cause adverse consequences. Any of these conditions could have a material adverse impact on our business, financial condition and results of operations.

We are subject to the risks of international trade, including possible import/export restrictions and fluctuations in foreign currency exchange rates.

Many significant components of the MelaFind system are manufactured by foreign suppliers and we also market MelaFind internationally. We may be subject to various import duties applicable to materials manufactured in foreign countries and, in addition, may be affected by various other import and export restrictions, as well as other considerations or developments impacting upon international trade, including economic or political instability, shipping delays and product quotas. These international trade factors may have an adverse impact on the cost of components and the prices we can charge for the MelaFind system. To the extent that transactions relating to the purchase of components and materials or the sale of products involve currencies other than U.S. dollars, our operating results will be affected by fluctuations in foreign currency exchange rates.

We will not be able to sell MelaFind unless its design verification and validation are maintained in accordance with current good manufacturing practices as set forth in the U.S. medical device Quality System Regulation ("QSR") and ISO 13485 certification.

Prior to the installation of the first commercial MelaFind system in March 2012, we completed all the steps necessary to verify and validate the design of the MelaFind system that were required to be performed prior to commercialization. If we are unable to maintain design verification and validation successfully, we will not be able to sell MelaFind, and we will not be able to meet our plans for the full commercialization of MelaFind. Later discovery of previously unknown problems with MelaFind, including manufacturing problems, or failure to comply with regulatory requirements such as the FDA QSR and ISO 13485, may result in restrictions on MelaFind or its manufacturing processes, withdrawal of MelaFind from the market, patient or physician notification, voluntary or mandatory recalls, fines, withdrawal of regulatory approvals, refusal to approve pending applications or supplements to approved applications, refusal to permit the import or export of our products, product seizures, injunctions or the imposition of civil or criminal penalties. Should any of these enforcement actions occur, our business, financial condition and results of operations could be materially and adversely affected.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with MelaFind, it could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continuous review and periodic inspections by the FDA and other regulatory bodies, including Germany ' s Federal Institute for Drugs and Medical Devices. In particular, we and our suppliers are required to comply with the QSR, ISO 13485 and other U.S. and European regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, promotion, distribution, and shipping of MelaFind. We also will be subject to ongoing U.S. and foreign regulatory requirements, including required submissions of safety and other post-market information and reports and registration and listing requirements. Furthermore, our third-party contract manufacturers will be required to adhere to current cGMP requirements enforced by the FDA as part of QSR, or similar regulations required by regulatory agencies in other countries. The manufacturing facilities of our contract manufacturers must be in full compliance with cGMP requirements. The FDA enforces the QSR and other regulatory requirements through unannounced inspections.

If we are found to be deficient in cGMP or QSR (or any applicable foreign rules and regulations), we could be subject to regulatory action of a type described below, which could negatively affect our ability to successfully commercialize MelaFind. There can be no assurance that the future interpretations of legal requirements made by the FDA or other U.S. or foreign regulatory bodies with possible retroactive effect, or the adoption of new requirements or policies, will not adversely affect us. We may be slow to adapt, or may not be able to adapt, to these changes or new requirements. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA, including those related to the detailed requirements associated with maintaining premarket application approvals, and other U.S. or foreign regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions: warning letters, fines and civil penalties, unanticipated expenditures, withdrawal of approval by the FDA or other regulatory bodies, product recall or seizure, interruption of production, operating restrictions, injunctions, and criminal prosecution. If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer.

We are involved in a heavily regulated sector, and our ability to remain viable will depend on favorable government decisions at various points by various agencies.

Healthcare is heavily regulated by national and regional governments, both in the U.S. and other countries. The laws and regulations affecting healthcare change constantly, thereby increasing the uncertainty and risk associated with any healthcare related venture, including our business and MelaFind.

For example, from time to time, legislation is introduced in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. 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.

The U.S. federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Federal Food, Drug, and Cosmetic Act, as well as other relevant laws; (ii) CMS, which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General ("OIG") which enforces various laws aimed at curtailing fraudulent or abusive practices, including by way of example, the Anti-Kickback Law, the Physician Self-Referral Law, commonly referred to as the Stark Law, the Anti-Inducement Law, the Civil Money Penalty Law, and the laws that authorize the OIG to exclude healthcare providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights, which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Public Health Service within HHS under the Public Health Service Act, the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under Medicaid and other state sponsored or funded programs and their internal laws regulating all healthcare activities.

In addition to regulation by the FDA as a medical device manufacturer, we are subject to general healthcare industry regulations. The healthcare industry is subject to extensive international, federal, state and local laws and regulations relating to:

- billing for services;
- quality of medical equipment and services;
- confidentiality, maintenance and security issues associated with medical records and individually identifiable health information;
- false claims; and
- labeling products.

These laws and regulations are extremely complex and, in some cases, still evolving. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations. If our operations are found to be in violation of any of the international, federal, state or local laws and regulations that govern our activities, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines or curtailment of our operations. The risk of being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business.

Legislation relating to medical devices may have a material adverse effect on us.

The Patient Protection and Affordable Care Act imposes significant new excise taxes on medical device transactions. Under the legislation, the total cost to the medical device industry is estimated to be approximately $20 billion over ten years. In January 2013, a 2.3% excise tax on medical devices went into effect as a component of the Patient Protection and Affordable Care Act. This tax along with the others in the Act will result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our results of operations and our cash flows. Other elements of this legislation such as comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business.

We must comply with complex statutes prohibiting fraud and abuse, and both we and physicians utilizing MelaFind 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 MelaFind by physicians may dissuade physicians from either purchasing or using MelaFind and could have a material adverse effect on our ability to successfully commercialize MelaFind.

The application of the privacy provisions of HIPAA is uncertain.

HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates "covered entities" (insurers, clearinghouses, and most healthcare providers) and indirectly regulates "business associates" with respect to the privacy of patients' medical information. Certain entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information. It is uncertain whether we would be deemed to be a covered entity under HIPAA, and it is unlikely that based on our current business model, we would be a business associate. Nevertheless, we may be contractually required to physically safeguard the integrity and security of the patient information that we or our physician customers receive, store, create or transmit. If we fail to adhere to our contractual commitments, then our physician customers may be subject to civil monetary penalties, and this could adversely affect our ability to market MelaFind. We also may be liable under state laws governing the privacy of health information.

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 MelaFind system 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 MelaFind® 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.

New product development in the medical device industry is both costly and labor intensive with very low success rates for successful commercialization; if we cannot successfully develop or obtain future products, our growth, beyond the growth related to MelaFind, would be delayed.

The product development process is time-consuming, unpredictable and costly. There can be no assurance that we will be able to develop or acquire new products, successfully complete any related clinical trials, obtain the necessary regulatory clearances or approvals required from the FDA on a timely basis, or at all, manufacture our potential products in compliance with regulatory requirements or in commercial volumes, or that, even if approved and manufactured, such potential products will achieve market acceptance. In addition, changes in regulatory policy for product approval during the period of product development, and regulatory agency review of each submitted new application, may cause delays or rejections. It may be necessary for us to enter into licensing arrangements in order to market effectively any new products or new indications for existing products. There can be no assurance that we will be successful in entering into such licensing arrangements on terms favorable to us or at all. Failure to develop, obtain necessary regulatory clearances or approvals for, or successfully market potential new products could have a material adverse effect on our business, financial condition and results of operations.

We face the risk of product liability claims and may not be able to obtain or maintain adequate insurance.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if MelaFind causes, or merely appears to have caused, an injury or if a patient alleges that MelaFind failed to provide appropriate evaluation information on a lesion where melanoma was subsequently found to be present. Claims may be made by patients, healthcare providers or others involved with MelaFind. Our coverage may not be adequate to protect us against any future product liability claims. If our insurance proves to be inadequate, we may not be protected against potential product liability claims and we will be exposed to significant liabilities which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

We may be subject to claims against us even if the apparent injury is due to the actions of others. For example, we rely on the expertise of dermatologists and other associated medical personnel to operate MelaFind. If these medical personnel are not properly trained or are negligent, we may be subjected to claims and ultimately liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in reduced acceptance of MelaFind in the market.

Insurance and surety companies have reassessed many aspects of their business and, as a result, may take actions that could negatively affect our business. These actions could include increasing insurance premiums, requiring higher self-insured retentions and deductibles, reducing limits, restricting coverage, imposing exclusions, and refusing to underwrite certain risks and classes of business. Any of these actions may adversely affect our ability to obtain appropriate insurance coverage at reasonable costs, which could have a material adverse effect on our business, financial condition and results of operations.

We may be adversely affected by a data center failure.

The success of MelaFind is dependent upon our ability to protect our data center against damage from fire, power loss, telecommunications failure, natural disaster, sabotage or a similar catastrophic event. Substantially all of our computer equipment and data operations are located in a single facility. Our prospective failure to maintain off-site copies of information contained in our MelaFind database, or our inability to use alternative sites in the event we experience a natural disaster, hardware or software malfunction or other interruption of our data center could adversely impact our business, financial condition and results of operations. While we do provide off-site back-up for our critical data, which we believe to be sufficient to meet our needs, there can be no assurance that our current plan can anticipate every possible eventuality.

We may be adversely affected by breaches of online security.

Our MelaFind lesion database does not contain any information that allows us to identify specific patients. However, we must identify certain data as belonging to or as derived from specific patients for regulatory, quality assurance and billing purposes. To the extent that our activities involve the storage and transmission of confidential information, security breaches could damage our reputation and expose us to a risk of loss, or to litigation and possible liability. Our business may be materially adversely affected if our security measures do not prevent security breaches. In addition, such information may be subject to HIPAA privacy and security regulations, the potential violation of which may trigger concerns by healthcare providers, which may adversely impact our business, financial condition and results of operations.

We are dependent upon telecommunications and the internet.

We use the internet to inform the public about the availability of our products and to market to and communicate with physicians who are potential or actual customers. Our success will therefore depend in part on the continued growth and use of the internet. If our ability to use the internet fails, it may materially adversely affect our business.

All of our operations are conducted at a single location. Any disruption at our facility could increase our expenses.

Substantially all of our operations are conducted at a single building in Irvington, New York. We take precautions to safeguard our facility, including insurance, health and safety protocols, contracted off-site engineering services, and storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations or cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

We may be liable for contamination or other harm caused by materials that we handle, and changes in environmental regulations could cause us to incur additional expense.

Our research and development and clinical processes do not generally involve the handling of potentially harmful biological materials or hazardous materials, but they may occasionally do so. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our business, financial condition and results of operations. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

Our success will depend on our ability to attract and retain our personnel.

Our success will depend on our ability to retain our current senior management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel.

Competition for senior management personnel, as well as scientists, clinicians, engineers, and experienced sales and marketing individuals, is intense, and we may not be able to retain our personnel. The loss of the services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the successful commercialization of MelaFind. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement.

If we are able to generate sufficient revenues to fund our current operations, we plan to expand our operations and grow our research and development, product development, administrative and marketing operations. This expansion would be expected to place a significant strain on our management, and would require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

Results could be impacted by the effects of, and changes in, world-wide economic and capital market conditions.

Our business may be adversely affected by factors in the United States and other countries, such as Germany and the other member states of the European Union, that are beyond our control, such as disruptions in the financial markets or downturns in economic activity. The current world-wide economic conditions could have an adverse impact on the availability and cost of capital, interest rates, tax rates, or regulations.

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 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 and costly. Since 2008, we have retained a consultant experienced in SOX that assists us in the process of monitoring and 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." 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.

Nasdaq has continued listing requirements that we must satisfy in order for our common stock to remain listed on Nasdaq. If our common stock were to be de-listed from Nasdaq, 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.

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If we fail to meet the applicable standards for continued listing, such as maintaining a minimum bid price of $1.00, our common stock may be delisted from the NASDAQ Capital Market. If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally by the Securities Exchange Commission as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

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

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

- failure of any of our products to achieve commercial success;
- the timing of regulatory approval for our future products;
- results of our research and development efforts and our clinical trials;
- the announcement of new products or product enhancements by us or our competitors;

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

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

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

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

- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- do not permit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and

· provide our board of directors the ability to designate the terms of and issue a new series of preferred stock without stockholder approval.

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

These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Risks Relating to Warrants Issued in the October 2013 and January 2014 Private Placement Transactions

We may incur significant non-operating, non-cash charges resulting from changes in the fair value of warrants.

In October 2013, we entered into a securities purchase agreement pursuant to which we issued Series A and Series B warrants to purchase up to 685,715 and 434,325 million shares of our common stock, respectively, and in January 2014, we entered into a securities purchase agreement pursuant to which we issued warrants to purchase up to 1,329,731 million shares of our common stock. The Series A warrants from October 2013 and all of the January 2014 warrants have been recorded at their respective relative fair values at the inception date of the respective agreement under which they were issued, and will be recorded at their respective fair values at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on our financial results. The fair value of the warrants is tied in large part to our stock price. If our stock price increases between reporting periods, the warrants become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

Risks Relating to the July 2014 Private Placement Transaction

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

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

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

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

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

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

We lease approximately 21,700 square feet of office, laboratory, and assembly space in a building with the street address of 50 South Buckhout Street, Suite 1, Irvington, New York 10533. The lease expires in December 2016. We believe that this facility is adequate to meet our current and reasonably foreseeable requirements. We believe that we will be able to obtain additional space, if required, on commercially reasonable terms. Manufacturing agreements with our contract manufacturers allow for the inclusion of charges for finished goods warehousing services as a component of their overhead charges.

Item 3. ***Legal Proceedings***

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

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information

Our common stock has been traded on the NASDAQ Capital Market since October 28, 2005, and since 2010 our ticker symbol has been MELA. Prior to 2005, there was no public market for our common stock. The following table sets forth the range of the high and low intraday prices for the period of January 1, 2013 through December 31, 2014 as reported by the NASDAQ Capital Market:

	High	Low
Year Ended December 31, 2014		
October 1 - December 31, 2014	$ 2.30	$ 1.11
July 1 - September 30, 2014	$ 3.50	$ 1.65
April 1 - June 30, 2014	$ 6.30	$ 3.10
January 1 - March 31, 2014	$ 8.90	$ 6.10
Year Ended December 31, 2013		
October 1 - December 31, 2013	$ 10.40	$ 6.30
July 1 - September 30, 2013	$ 10.70	$ 6.50
April 1 - June 30, 2013	$ 13.90	$ 7.00
January 1 - March 31, 2013	$ 21.90	$ 10.80

As of January 31, 2015, there were approximately 54 holders of record of our common stock. This number does not include the number of persons whose shares are in nominee or in "street name" accounts through brokers.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain our cash for the development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on then existing conditions, including our earnings, financial condition, results of operations, level of indebtedness, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our board of directors' ability to declare a dividend is also subject to limits imposed by Delaware law.

Securities Authorized For Issuance Under Equity Compensation Plans

Plan Category at 12/31/2014	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available under equity compensation plans (excluding securities reflected in the first column)
Equity compensation plans approved by stockholders	1,308,835	$ 2.76	2,301,691
Equity compensation plans not approved by stockholders	—	—	—
Total	1,308,835	$ 2.76	2,301,691

Item 6. ***Selected Financial Data***

Not applicable.

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

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth above under the caption "Risk Factors". You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements for the year ended December 31, 2014 and the related notes appearing in Part II Item 8 of this report.

Overview

We are a medical device company dedicated to designing and developing innovative software-driven technology for the early detection and prevention of skin cancer. We are focused on the commercialization of our flagship product, the MelaFind System, or MelaFind, as well as the further design and development of this technology. MelaFind is a non-invasive, point-of-care (i.e. in the doctor's office) instrument to aid in the detection of melanoma. The System features a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated classification algorithms, 'trained' by our proprietary database of melanomas and benign lesions. This result provides information to assist in the management of the patient's disease, including information useful in the decision on whether to biopsy the lesion.

In November 2011, we received a PMA from the FDA for MelaFind, having already received CE Mark approval in September 2011 in Europe. On March 7, 2012, we installed the first commercial MelaFind System. We initially marketed the MelaFind System primarily to aesthetic dermatologists through a lease program in which users paid an upfront placement fee and periodic usage fees. In 2013, because our launch objectives were not realized, we reviewed our marketing strategy. Revenues amounting to $0.5 million and $0.3 million in 2013 and 2012, respectively, did not meet our expectations, and due to the nature of the lease agreements we continued to record high cost of sales. We implemented a significant cost reduction program in 2013 that affected all areas of our business, and which continued throughout 2014. As a result of our strategy review in 2013, we undertook several steps that we believe will significantly improve MelaFind's commercial acceptance: 1) we elected to change our business model from solely a rental-based model to include a capital sales option; 2) we refocused our marketing efforts on medical dermatology, and particularly those dermatologists who treat patients at high risk for melanoma; and 3) we began the process of obtaining a coverage determination from the CMS, the federal agency that administers Medicare, in order to obtain reimbursement by Medicare and ultimately by private insurers for the use of MelaFind. During 2014, we made progress in each of these areas, although we anticipate that it will require several years of continued effort before the success of this strategy can be assessed.

In July 2014, we announced that we took the first step in the process of obtaining insurance reimbursement for our multi-spectral digital skin lesion analysis ("MSDSLA") procedure that is performed by dermatologists utilizing the MelaFind system as an aid in the detection of melanoma. On March 9, 2015, the February 2015 CPT® Editorial Summary of Panel Actions was posted to the website of the AMA. The CPT Editorial Panel accepted the addition of Category III codes 039XX1T and 039XX2T to report MSDSLA of atypical cutaneous lesions. Barring any further action by the Panel, we expect that these codes will be posted to the AMA CPT website by July 1, 2015 with an effective date of January 1, 2016 and will provide the basis for pursuing third party and CMS insurance coverage for MelaFind. We plan to commence efforts to obtain reimbursement from private insurers, which could take several years to complete.

Until we obtain insurance reimbursement from the CMS and private insurers, we expect that our revenues will not be sufficient to cover our anticipated operating and other expenses. Our financial success will depend on a number of factors, primary among which is our ability to sell MelaFind systems, increase the penetration with dermatologists, encourage the usage of these systems, and control our costs. Currently, we cannot determine when we will have sufficient revenues to cover our continuing developmental costs, manufacturing, marketing and other operational expenses.

We are continually evaluating potential enhancments to the capabilities of the MelaFind system. During the third quarter of 2014, we implemented changes to the system aimed at reducing manufacturing material costs, test labor and cycle time.

Our PAS is evaluating the sensitivity and false positive rate of physicians after using the MelaFind system with their performance if MelaFind was not available. The study is currently enrolling patients and we are targeting submission of the PAS report to the FDA by year-end 2018.

In February 2014, we sold for net proceeds of $11.4 million (i) an aggregate of 12,300 shares of Series A Convertible Preferred Stock (the "Series A Preferred Stock"), convertible into 1.5 million shares of common stock at a conversion price of $8.40, and (ii) warrants to purchase up to 1.3 million shares of common stock. In addition, as a condition of the financing, our directors purchased an aggregate of 20,271 shares of common stock, at a price of $7.40 per share, for aggregate gross proceeds of $150,000.

In connection with this financing, we also granted to the purchasers' resale registration rights with respect to the shares of common stock underlying the Series A Preferred Stock and the warrants pursuant to the terms of a Registration Rights Agreement. The investors were entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, effectiveness and maintaining an effective registration statement covering the shares underlying the Series A Preferred Stock and the warrants. We were unable to meet certain filing and effectiveness requirements and as a result paid liquidated damages to the Purchasers in the aggregate amount of approximately $3.4 million.

In July 2014, we raised additional net proceeds of approximately $13.8 million through the issuance of 4% senior secured convertible debentures due July 2019 (the "Debentures") and 6.2 million warrants expiring five years from the date of issuance (the "July 2014 Series A warrants"). The Debentures are convertible at any time into an aggregate of approximately 5.8 million shares of our common stock at a price of $2.565 per share. Our obligations under the Debentures are secured by a first priority lien on all of our intellectual property. In connection with the transaction, we also exchanged 12,300 shares of Series B Preferred Stock, convertible at any time into an aggregate of approximately 4.8 million shares of common stock at a conversion price of $2.565 per share, for all of our outstanding Series A Preferred Stock that was issued in February 2014. We also issued warrants to purchase common stock at an exercise price of $2.45 per share, with 4.8 million warrants expiring in eighteen months from the date of issuance (the "July 2014 Series B Warrants"). In September 2014, we amended the registration statement related to the Series A Preferred Stock to deregister those shares that would have been issuable upon conversion of the Series A Preferred Stock. We entered into a Registration Rights Agreement with the investors pursuant to which we were obligated to file a registration statement to register the resale of the shares of common stock issuable upon conversion of the Series B Preferred Stock and Debentures and upon exercise of the warrants. The registration statement was declared effective in October 2014.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our judgments related to accounting estimates. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 3 to our financial statements included in this annual report, we believe that the following accounting policies and significant judgments and estimates relating to revenue recognition, stock-based compensation charges, and fair value of warrants are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

We consider revenue to be earned when all of the following criteria are met: persuasive evidence a sales arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. Our agreements with dermatologists regarding the MelaFind system combine the elements noted above with a future service obligation. Under our leased-based model, we placed the MelaFind systems with dermatologists for their exclusive use, but retained ownership of the MelaFind systems.

During 2013 and 2014, under the leased-based method, we generated revenue from usage based on the number of patient sessions and lesions examined. Additionally, we typically charged an initial installation fee for each MelaFind system which covered training, delivery, initial supplies, maintenance and the right to use the MelaFind system. In accordance with the accounting guidance regarding multiple-element arrangements, we allocated total contract consideration to each element based upon the relative standalone selling prices of each element, and recognized the associated revenue for each element as delivery occurred or over the related service period, generally expected to be two years. Revenues associated with undelivered elements were deferred until delivery occurred or services rendered. The significant judgments we made related to allocation of the contract consideration to each element whereby changes in the standalone selling price could impact the amount of revenue recognized in a specific period and estimates of uncollectible accounts receivables.

In December 2013, we amended our business model from solely a leased-based model to include a capital sales option for the MelaFind system. Under this model, we recognize revenues for product sales when title and risk of loss transfers to customers, which is after installation and training, and when reliable estimates of sales allowances and warranties can be made and collectability is reasonably assured. We will regularly review the information related to these estimates and adjust the reserves accordingly.

Inventories

Inventories consist of finished products and raw materials that are stated at the lower of cost (first-in, first-out) or market value. We reserve for specific inventory items that are no longer being used in the devices and monitor this at each reporting date.

Throughout the year, we deferred repairs of certain of our MelaFind system units that we determined were unlikely to be sold during the next several periods. We estimated the cost to restore our system units to sellable condition and created a repair reserve amounting to $0.5 million at December 31, 2014.

Stock-Based Compensation

We record compensation expense associated with stock options, restricted stock awards and other forms of equity compensation in accordance with FASB ASC 718, *Compensation-Stock Compensation*. The fair value of an equity award is determined at the date of grant using the Black-Scholes Model and the fair value of the equity award is expensed over the service period. The most significant inputs used to value an equity award include current stock price, the amount the employee must pay to acquire the equity award, volatility rate, interest rate and estimated term. For equity awards that vest upon achieving a defined milestone, the underlying compensation charge is recorded when it is probable that the milestone will be achieved. It is then amortized over the estimated period to satisfy vesting requirements. The probability of vesting is updated at each reporting period and compensation is adjusted accordingly. The significant judgments relate to the assumptions used in the valuation model to determine the fair value of the equity instrument including the volatility rate, term and interest rate. Any increases (decreases) in either of the volatility rate, the term or the interest rate would increase (decrease) the value of the equity instrument and the corresponding compensation expense recognized each period. Estimates of performance based awards vesting can also have a significant impact on recognized stock compensation as the likelihood of a performance based award vesting can change from period-to-period with changes in estimates included in current period operations.

Fair Value Measurements

We have adopted the provisions of FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*" for financial instruments. This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. ASC 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. ASC 820 permits an entity to measure certain financial assets and financial liabilities at fair value with changes in fair value recognized in earnings each period.

ASC 820 establishes a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. Level 2 inputs are inputs other than quoted prices included in Level 1 that are directly or indirectly observable for the asset or liability. Such inputs include quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability, or inputs derived principally from or corroborated by observable market data by correlation or other means. Level 3 inputs are unobservable inputs for the asset or liability. Such inputs are used to measure fair value when observable inputs are not available.

Warrant Liability

We account for the 685,715 common stock warrants issued in connection with the October 31, 2013 financing and the 1,329,731 common stock warrants issued in connection with the February 2014 financing in accordance with the guidance contained in ASC 815-40-15-7D, "*Contracts in Entity's Own Equity*" whereby under that provision they do not meet the criteria for equity treatment and must be recorded as a liability because they have non-standard terms in relation to a fundamental transaction and require a net cash settlement upon a change in control. Accordingly, we classified the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised or expiration, and any change in fair value is recognized in our statements of operations. The fair value of warrants issued by us in connection with the transaction has been estimated using an option pricing model. We also accounted for 69,321 common stock warrants that were issued in connection with our debt financing during the year ended December 31, 2013, as a liability until we increased our authorized number of shares at the 2013 Annual Meeting of Stockholders and then reclassified those warrants into equity.

Recently Issued Accounting Standards

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update "ASU" No. 2014-15 on "*Presentation of Financial Statements Going Concern (Subtopic 205-40)* – Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". Currently, there is no guidance in U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in this update provide that guidance. In doing so, the amendments are intended to reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this update are effective for annual periods ending after December 15, 2016. Early adoption is permitted. We are currently evaluating the new guidance to determine the impact the adoption of this guidance will have on our results of operations, cash flows or financial condition.

In May 2014, the FASB issued ASU No. 2014-09, "*Revenue from Contracts with Customers (Topic 606*)." ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. ASU 2014-09 is effective for public entities for annual reporting periods beginning after December 15, 2016 and interim periods within those periods. Early adoption is not permitted. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. We are currently assessing the impact that adopting this new accounting guidance will have on our consolidated financial statements and footnote disclosures.

Year Ended December 31, 2014 Compared with Year Ended December 31, 2013

Revenue

Revenue increased $0.4 million, or 80%, to $0.9 million for the year ended December 31, 2014 compared with revenue of $0.5 million for the year ended December 31, 2013. This increase is the result of $0.5 million in Melafind system sales revenue under our capital sales model, partially offset by a decline in deferred placement revenue. Our first commercial sale occurred in the second quarter of 2014. No new lease agreements were signed in 2014.

Cost of Revenue

Cost of revenue increased $0.6 million, or 14%, to $4.9 million for the year ended December 31, 2014 compared with $4.3 million for the year ended December 31, 2013. This increase is primarily due to an increase of $1.1 million of inventory reserves resulting from improvements made in the design of the MelaFind sysem, our decision to defer repairs of certain of our MelaFind system units that we determined were unlikely to be sold during the next several periods, and an increase of $0.4 million in cost of MelaFind systems sold under our capital sale model. This was offset by approximately $0.6 million in reduced depreciation expense and $0.3 million in various other items.

Costs of revenue were primarily made up of direct costs associated with the manufacture of the units sold during the year, technical support costs and depreciation expense of the MelaFind systems leased. Certain product quality and manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind are allocated to costs of goods sold.

Research and Development Expense

Research and development ("R&D") expenses decreased 58% to approximately $1.6 million for the year ended December 31, 2014 compared with $3.8 million for the year ended December 31, 2013. The decrease is the result the cost reduction plan initiated in August 2013. Ongoing R&D efforts are concentrating on future product enhancements.

Selling, General and Administrative Expense

Selling, general and administrative ("SG&A") expenses decreased $4.5 million, or 29%, to approximately $11.0 million for the year ended December 31, 2014 compared with $15.5 million for the year ended December 31, 2013. The decrease is the result of salary and headcount decreases, as well as a reduction in stock based compensation expense, decreases in consulting and temporary help and further cost reduction initiatives.

Impairment of Long-lived Assets

During year ended December 31, 2013, our marketing focus shifted to large cancer centers and high risk patients, and we recorded an impairment charge of approximately $1.0 million against our MelaFind systems previously placed in locations that did not fit this profile. We anticipate that the affected systems will ultimately be redeployed.

Interest Expense

Interest expense increased to $2.4 million for the year ended December 31, 2014 compared with $0.6 million for the year ended December 31, 2013. In 2014, interest expense related primarily to the issuance of our 4% Convertible Debentures in July and the subsequent conversion of approximately $1.6 million in Debentures in October 2014, and included $1.9 million in amortization of debt discount, $0.3 million in interest payments, and $0.2 million in amortization of deferred financing costs. The conversion of the Debentures resulted in approximately $1.2 million of accelerated interest expense included in the total. In 2013, interest expense was incurred by a $6 million senior debt financing we raised in March 2013 and prepaid in September 2013 (See Footnote 9 "Debt").

Change in Fair Value of Warrant Liability

The change in fair value of our warrant liability is a benefit of $8.1 million for the year ended December 31, 2014, compared to a charge of $0.3 million for the year ended December 31, 2013. The change is primarily due to additional liability warrants being issued in the February 2014 financing, with the current benefit being directly related to the reduction in our stock price for the period (See Note 10 "Recurring Fair Value Measurements").

Write-off of Unamortized Loan Costs

On March 15, 2013, we executed loan documents with Hercules Technology Growth Capital Inc., a venture capital lender, whereby we borrowed $6.0 million. As the result of our election to prepay the loan on September 10, 2013, the unamortized loan discount, fee and deferred financing costs were expensed resulting in a write-off of unamortized loan costs of approximately $1.0 million (see Note 9 "Debt").

Registration Rights Liquidating Damages

In connection with the February 5, 2014 financing, we granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Series A Preferred Stock and the warrants pursuant to the terms of a Registration Rights Agreement. Pursuant to the agreement, the Purchasers were entitled to receive liquidated damages upon the occurrence of each of a series of events relating to filing, getting effective and maintaining an effective registration statement covering the shares underlying the Series A Preferred Stock and the warrants, including the failure to file a resale registration statement by no later than February 25, 2014 and the failure to have such resale registration statement declared effective by the SEC no later than March 7, 2014. The liquidated damages were payable upon the occurrence of each of those events and each monthly anniversary thereof until cured up to a total of 32% of the aggregate purchase price paid by each Purchaser. The liquidated damages were prorated on a daily basis for each event until such event was cured. We were unable to file the initial re-sale registration statement by February 25, 2014 or have it declared effective by March 7, 2014 and as a result paid liquidated damages to the Purchasers in the aggregate amount of $3.4 million.

Other Income

Other income for the year ended December 31, 2014 and 2013 was $0.2 million and $21,000, respectively, and represents royalty income we earn each quarter from Kavo Dental GmbH on the sale/licensing of our DIFOTI product. During the twelve months ended December 31, 2014, we received back royalty payments and interest on actual unit sales compared with the minimum royalty payment of $5,000 per quarter we recorded in 2013.

Cash Flows from Operating Activities

Net cash used in operations was $17.7 million for the year ended December 31, 2014. For the year ended December 31, 2013, the net cash used in operations was $19.4 million. In both periods, cash used in operations was attributable to net losses after an adjustment for non-cash charges, principally related to the change in fair value of warrant liability, inventory reserves, depreciation/amortization and share-based compensation, and other changes in operating assets and liabilities. Net cash used in operations for the period ended December 31, 2014 includes $3.4 million in liquidating damages that were paid to the purchasers in our February 2014 financing.

Cash Flows from Investing Activities

Net cash used in investing activities was $17,000 for the year ended December 31, 2014 and represents proceeds from the sale of fixed assets. Net cash used in investing activities was $5.2 million for the year ended December 31, 2013 principally relating to the purchase of fixed assets, which are primarily MelaFind systems.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2014, was $25.3 million representing net proceeds of $11.5 million from our February 2014 financing, and $13.8 million in net proceeds from the issuance of debentures issued in July 2014. Net cash provided by financing activities was $20.5 million for the year ended December 31, 2013, and reflects the net proceeds received from our public and private sales of common stock and proceeds from the exercise of common stock options.

Liquidity and Capital Resources

From inception, we have financed our operations primarily through the use of working capital from the sale of debt and equity securities. As of December 31, 2014, we had $11.4 million in cash and cash equivalents compared with $3.8 million at December 31, 2013. The $7.6 million increase reflects $25.3 million of net cash provided by 2014 financing activities offset by $17.7 million of net cash used in operating activities. Our cash and cash equivalents at December 31, 2014 are liquid investments in cash with two commercial banks and money market accounts held in accounts that substantially exceed FDIC limits.

On February 5, 2014, pursuant to a securities purchase agreement dated as of January 31, 2014, we sold to the Purchasers (i) an aggregate of 12,300 shares of Series A Preferred Stock, par value $0.10 and a stated value of $1,000 per share, convertible into 1,464,287 shares of common stock at an initial conversion price of $8.40, and (ii) warrants to purchase up to 1,329,731 shares of common stock for net proceeds of approximately $11.5 million. The warrants have an exercise price of $7.40 per share, are immediately exercisable and have a term of five years. These warrants have non-standard terms as they relate to a fundamental transaction and require a net-cash settlement upon a change in control and therefore are classified as a derivative liability and recorded at fair value on the inception date of February 5, 2014. They will be recorded at their respective fair value at each subsequent balance sheet date. Also, in connection with this financing, we were unable to file the initial re-sale registration statement by February 25, 2014 or have it declared effective by March 7, 2014 and therefore paid liquidated damages to the Purchasers in the aggregate amount of $3.4 million.

On July 21, 2014, we entered into a definitive Securities Purchase Agreement (the "Purchase Agreement") with institutional investors (the "Investors") providing for the issuance of Senior Secured Convertible Debentures in the aggregate principal amount of $15 million, due, subject to the terms therein, in July 2019 (the "Debentures"), and warrants (the "July 2014 Series A Warrants") to purchase up to an aggregate of 6,198,832 shares of common stock at an exercise price of $2.45 per share expiring in July 2019. Proceeds from the Debentures are being used for general working capital purposes.

Additionally, in connection with the Purchase Agreement we exchanged with certain investors, 12,300 of Series A convertible preferred stock issued on February 5, 2014 for 12,300 shares of Series B convertible preferred stock, par value $0.10 and a stated value of $1,000 per share (the "Series B Preferred Stock"), and warrants (the "July 2014 Series B Warrants") to purchase up to an aggregate of 4,795,321 shares of common stock at an exercise price of $2.45 per share expiring in January 2016. The offering closed on July 24, 2014.

We have experienced recurring losses and negative cash flow from operations. These recurring losses raise substantial doubt about our ability to continue as a going concern. We expect these conditions to continue for the foreseeable future. We have been and continue to be dependent on raising capital from the sale of securities in order to continue to operate and to meet our obligations in the ordinary course of business. We may need to raise funds in the future to support our sales and marketing of the MelaFind system, further advances in the MelaFind technology and to support clinical trials. The timing and amount of any additional funding we may seek will be affected by numerous factors, many of which are not under our control. There can be no assurance that additional financing will be available in the future at an acceptable cost, or at all.

Operating Capital and Capital Expenditure Requirements

We face certain risks and uncertainties that are present in many emerging medical device companies. At December 31, 2014, we had an accumulated deficit of $182.3 million. We will continue to incur expenses in connection with our commercialization and development activities related to MelaFind. We expect to incur clinical, marketing and sales expenses plus additional contract manufacturing and inventory costs over the next several years which will require additional funding. We cannot determine at this time when we will generate any significant revenues.

If our existing cash is insufficient to satisfy our liquidity requirements, we may seek to sell additional debt or equity securities. If additional funds are raised through the issuance of debt securities, these securities would have rights senior to those associated with our common stock and could contain covenants that may restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of, delay or eliminate some or all of, planned product research development and commercialization activities, which could harm our business.

Our future funding requirements will depend on many factors, including, but not limited to:

- the cost of commercialization activities, including support of the current domestic direct sales force and conducting activities in Germany and ultimately in other countries;
- the cost of implementing ourmarketing strategy;
- sales of MelaFind units;
- the amount of direct payments we are able to obtain from physicians utilizing MelaFind;
- the costs of maintaining regulatory approval;
- reimbursement amounts for the use of MelaFind that we are able to obtain from Medicare and third party payers;
- the success of our research and development efforts in product creation and enhancement, and meeting competitive services and technologies;
- the schedule, costs, and results of our clinical trials including the Post-Approval Study;
- the costs of maintaining our inventory and other manufacturing expenses and possible write-downs of obsolete inventory;
- our ability to establish and maintain any collaborative, licensing or other arrangements, and the terms and timing of any such arrangements;
- the costs involved in defending any patent infringement actions or other litigation claims brought against us by third parties; and
- the costs of filing, prosecuting, defending and enforcing any patent claims or other rights.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

Not applicable

Item 8. ***Financial Statements and Supplementary Data***

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
MELA Sciences, Inc.

We have audited the accompanying balance sheets of MELA Sciences, Inc. as of December 31, 2014 and 2013, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of MELA Sciences, Inc., as of December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EisnerAmper LLP

New York, New York
March 27, 2015

MELA SCIENCES, INC.
BALANCE SHEETS
(in thousands, except for share data)

	December 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,434	$ 3,783
Accounts receivable (net of allowance of $95 and $46 as of December 31, 2014 and 2013, respectively)	220	57
Inventory (net of reserve $1,409 and $325 as of December 31, 2014 and 2013, respectively) (See Note 4)	5,275	5,631
Prepaid expenses and other current assets	274	880
Total Current Assets	17,203	10,351
Property and equipment, net (See Note 5)	1,961	3,691
Patents and trademarks, net	37	42
Deferred financing costs	821	-
Other assets	48	48
Total Assets	**$ 20,070**	**$ 14,132**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable (includes related parties of $74 and $33 as of December 31, 2014 and 2013, respectively)	$ 1,240	$ 1,479
Accrued expenses (includes related parties of $0 and $48 as of December 31, 2014 and 2013, respectively)	842	844
Deferred revenue	43	244
Warrant liability (See Note 10)	499	3,017
Other current liabilities	62	68
Total Current Liabilities	2,686	5,652
Long-Term Liabilities:		
Deferred revenue	27	64
Deferred rent	80	120
Senior secured convertible debentures (net of discount of $8,410 at December 31, 2014)	5,001	-
Total Long-Term Liabilities	5,108	184
Total Liabilities	**7,794**	**5,836**
COMMITMENTS AND CONTINGENCIES		
Stockholders' Equity:		
Series B convertible preferred stock - $0.10 par value; authorized 10,000,000 shares: issued and outstanding: 11,787 and 0 at December 31, 2014 and 2013, respectively	1	-
Common stock - $0.001 par value; authorized 50,000,000 shares:		
Issued and outstanding 6,037,232 and 4,750,160 shares at December 31, 2014 and 2013, respectively.	6	5
Additional paid-in capital	194,562	176,439
Accumulated deficit	(182,293)	(168,148)
Total Stockholders' Equity	12,276	8,296
Total Liabilities and Stockholders' Equity	**$ 20,070**	**$ 14,132**

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.
STATEMENTS OF OPERATIONS
(in thousands, except for share and per share data)

	December 31, 2014	December 31, 2013
Net revenues	$ 915	$ 536
Cost of revenue	4,935	4,341
Gross profit	**(4,020)**	**(3,805)**
Operating expenses:		
Research and development	1,641	3,782
Selling, general and administrative	10,961	15,536
Impairment of long-lived assets	-	1,011
Total operating expenses	12,602	20,329
Operating loss	**(16,622)**	**(24,134)**
Other income (expenses):		
Interest income	8	8
Interest expense	(2,380)	(564)
Change in fair value of warrant liability	8,103	(296)
Write-off of unamortized loan costs	-	(983)
Gain on sale of fixed assets	16	-
Registration rights liquidated damages	(3,420)	-
Other income, net	150	21
	2,477	(1,814)
Net loss	**$ (14,145)**	**$ (25,948)**
Deemed dividend related to beneficial conversion feature on convertible preferred stock	(1,887)	$ -
Net loss attributable to common stockholders	**$ (16,032)**	**$ (25,948)**
Basic and diluted net loss per common share	$ (3.03)	$ (6.05)
Basic and diluted weighted average number of common shares outstanding	5,295,929	4,289,450

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.
STATEMENT OF STOCKHOLDERS' EQUITY
Years ended December 31, 2013 and 2014
(in thousands)

	Convertible Preferred Stock								
	Series A		Series B		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2013	-	-	-	-	**3,220**	**3**	**156,172**	**(142,200)**	**13,975**
Issuance of shares of common stock in connection with a public offering (net of issuance costs of $1,025)	-	-	-	-	1,081	1	15,724	-	15,725
Issuance of shares of common stock and warrants in connection with an October 2013 private placement (net of issuance costs of $3,426)	-	-	-	-	423	1	2,572	-	2,573
Warrants issued in connection with loans payable	-	-	-	-	-	-	652	-	652
Exercise of options	-	-	-	-	2		18	-	18
Share-based compensation expense	-	-	-	-	24	-	1,301	-	1,301
Net loss	-	-	-	-	-	-	-	(25,948)	(25,948)
Balance at December 31, 2013	-	-	-	-	**4,750**	**$ 5**	**$ 176,439**	**$ (168,148)**	**$ 8,296**
Issuance of Series A convertible preferred stock and common stock in connection with the February 2014 private placement (net of issuance costs of $992)	12	1	-	-	20	-	11,457	-	11,458
Issuance of warrants in connection with the February 2014 private placement	-	-	-	-	-	-	(5,585)	-	(5,585)
Issuance of Series B convertible preferred stock in connection with the July 2014 private placement	-	-	12	1	-	-	-	-	1
Expenses related to the issuance of Series B convertible preferred stock in connection with the July 2014 private placement	-	-	-	-	-	-	(103)	-	(103)
Warrants and beneficial conversion feature issued with senior secured debentures	-	-	-	-	-	-	10,353	-	10,353
Redemption of Series A convertible preferred stock in connection with the July 2014 private placement	(12)	(1)	-	-	-	-	-	-	(1)
Beneficial conversion feauture related to Series B convertible preferred stock	-	-	-	1,887	-	-	(1,887)	-	-
Accretion of discount on Series B convertible preferred stock	-	-	-	(1,887)	-	-	1,887	-	-
Conversion of 0.5 shares of Series B convertible preferred stock	-	-	(1)	-	200	-	-	-	-
Conversion of $1,589 in convertible debentures	-	-	-	-	620	1	1,588	-	1,589
Exercise of prefunded warrants	-	-	-	-	434	-	-	-	-
Share-based compensation expense	-	-	-	-	13	-	413	-	413
Net loss	-	-	-	-	-	-	-	(14,145)	(14,145)
Balance at December 31, 2014	-	-	**11**	**$ 1**	**6,037**	**$ 6**	**$ 194,562**	**$ (182,293)**	**$ 12,276**

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	December 31, 2014	December 31, 2013
Cash flows from operating activities:		
Net loss	$ (14,145)	$ (25,948)
Adjustments to reconcile net loss:		
Write-off of unamortized loan costs	-	983
Depreciation and amortization	1,790	2,439
Impairment of long-lived assets	-	1,011
Bad debt expense	52	46
Write-off of unamortized financing costs	-	41
Share-based compensation expense	413	1,301
Amortization of deferred financing costs	191	250
Amortization of debt discount	1,943	-
Change in fair value of warrant liability	(8,103)	296
Inventory reserve	1,084	325
Gain on sale of fixed assets	(16)	-
Changes in operating assets and liabilities:		
Accounts receivable	(215)	77
Inventory	(784)	121
Prepaid expenses and other current assets	606	86
Other assets	-	36
Accounts payable and accrued expenses	(241)	(484)
Other current liabilities	(6)	27
Deferred rent	(40)	(24)
Deferred revenue	(238)	4
Net cash used in operating activities	**(17,709)**	**(19,413)**
Cash flows from investing activities:		
Purchases of property and equipment	-	(5,188)
Proceeds from the sale of fixed assets	17	-
Net cash provided by (used in) investing activities	**17**	**(5,188)**
Cash flows from financing activities:		
Net proceeds from private placements/public offerings	11,458	21,174
Proceeds from long-term debt	15,000	6,000
Expenses related to long-term debt	(1,012)	(245)
Expenses related to issuance of Series B convertible preferred stock	(103)	-
Repayment of long-term debt	-	(6,425)
Proceeds from exercise of stock options	-	18
Net cash provided by financing activities	**25,343**	**20,522**
Net increase (decrease) in cash and cash equivalents	7,651	(4,079)
Cash and cash equivalents at beginning of period	**3,783**	**7,862**
Cash and cash equivalents at end of period	**$ 11,434**	**$ 3,783**
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	$ 116	$ -
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Conversion of convertible preferred stock into common stock	$ 513	$ -
Conversion of senior secured convertible debentures into common stock	$ 1,589	$ -
Recognition of debt discount on senior secured convertible debentures	$ 5,788	$ -
Recognition of beneficial conversion feature on senior secured convertible debentures	$ 4,565	$ -
Exchange of series A convertible preferred stock for series B convertible preferred stock	$ 12,300	$ -
Reclassification of warrant liability to stockholders equity	$ -	$ 652
Reclassification of MelaFind components between property and equipment and inventory	$ -	$ 5,402

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.
Notes to Financial Statements
(In thousands, except for share and per share data)

1. Principal Business Activities

Organization and Business

MELA Sciences, Inc., a Delaware corporation (the "Company"), is a medical device company dedicated to designing and developing innovative software-driven technology for the early detection and prevention of skin cancer. The Company is focused on the commercialization of its flagship product, the MelaFind® System, or MelaFind, as well as the further design and development of this technology. MelaFind is a non-invasive, point-of-care (in the doctor's office) instrument to aid in the detection of melanoma. The system features a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated classification algorithms, "trained" by our proprietary database of melanomas and benign lesions. This result provides information to assist in the management of the patient's disease, including information useful in the decision of whether to biopsy the lesion.

MelaFind's components include:

- a *hand-held imager*, which employs high precision optics and multi-spectral illumination (multiple wavelengths of light);
- a *proprietary database* of pigmented skin lesions, believed to be the largest prospective database to date in the U.S.; and
- *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions.

In November 2011, the Company received a Pre-Market Approval, or PMA, from the U.S. Food and Drug Administration ("FDA") for MelaFind, having already received Conformité Européenne ("CE") Mark approval in September 2011. On March 7, 2012, the Company installed the first commercial MelaFind System. The Company initially marketed the MelaFind System primarily to aesthetic dermatologists through a lease program in which users paid an upfront placement fee and periodic fees for use. In 2013, because the launch objectives were not realized, the Company reviewed its marketing strategy. Revenues amounting to $536 and $278 in 2013 and 2012, respectively, did not meet expectations, and due to the nature of the lease agreements the Company continued to record high cost of sales. The Company implemented a significant cost reduction program in 2013 that affected all areas of its business, and which continued throughout 2014. As a result of this strategy review in 2013, the Company undertook several steps that it believes will significantly improve MelaFind's commercial acceptance by: 1) changing its business model from solely a rental-based model to include a capital sales option; 2) refocusing its marketing efforts on medical dermatology, and particularly those dermatologists who treat patients at high risk for melanoma; and 3) beginning the process of obtaining a coverage determination from the Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers Medicare, in order to obtain reimbursement by Medicare and ultimately by private insurers for the use of MelaFind. During 2014 the Company made significant strides in each of these areas, although it anticipates that it will require a few years of continued effort before the success of this strategy can be assessed. The Company anticipates that the insurance reimbursement process could take several years to complete.

In July 2014, the Company announced that it took the first step in the process of obtaining insurance reimbursement for its Multi-Spectral Digital Skin Lesion Analysis ("MSDSLA") procedure that is performed by dermatologists utilizing the MelaFind system as an aid in the detection of melanoma. The Company submitted an application for a CPT code, which is necessary for Medicare Part B reimbursement by the CMS. On March 9, 2015, the February 2015 CPT® Editorial Summary of Panel Actions was posted to the website of the American Medical Association (the "AMA"). The CPT Editorial Panel accepted the addition of Category III codes 039XX1T and 039XX2T to report MSDSLA of atypical cutaneous lesions, which applies to the MelaFind System. Barring any further action by the Panel, the Company expects that these codes will be posted to the AMA CPT website by July 1, 2015 with an effective date of January 1, 2016 and will provide the basis for pursuing third party and CMS insurance coverage for MelaFind. The Company plans to commence efforts to obtain reimbursement from private insurers, which could take several years to complete.

Until the Company obtains insurance reimbursement from the CMS and private insurers, it expects that revenues will not be sufficient to cover operating and other expenses. The Company's financial success will depend on a number of factors, primary among which is the ability to sell MelaFind systems, increase the penetration with dermatologists, encourage the usage of these systems, and control costs. Currently, the Company cannot determine when it will have sufficient revenues to cover continuing developmental costs, manufacturing, marketing and other operational expenses.

2. Basis of Presentation

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Liquidity and Going Concern

The Company has experienced recurring losses and negative cash flow from operations and management expects these conditions to continue for the foreseeable future. As the result of these factors, the Company has been and continues to be dependent on raising capital from the sale of securities in order to continue to operate and to meet its obligations in the ordinary course of business. In mid-year 2013, management put in place a cost reduction program that included staff reductions, the elimination or deferral of all nonessential projects and activities and the scaling back or discontinuance of general corporate activities (referred to as "Cost Reduction Plan") to preserve liquidity. In addition, in February 2014, the Company raised net proceeds of approximately $11,458 from the sale of convertible preferred stock, common stock and warrants and in July 2014, the Company raised proceeds of approximately $15,000 from the sale of senior secured convertible debentures, convertible preferred stock and warrants to strengthen the Company's financial position.

The Company continues to incur net losses. These net losses have had a significant negative impact on the Company's working capital and financial position and may impact its future ability to meet its obligations in the ordinary course of business. As a result, management believes that, even with cash and cash equivalents held at December 31, 2014, and estimated revenue, there is significant doubt about its ability to continue as a going concern. The Company continues to assess the effects of its previously announced Cost Reduction Plan and is prepared to further reduce various operational costs as necessary. Although the Company has no specific arrangements or plans, the Company will need additional capital during the next 12 months.

The Company expects to incur additional medical, marketing and sales expenses as well as additional contract manufacturing and inventory costs in the future that will require additional funding. As a result, the Company expects to continue to incur operating losses for the foreseeable future and cannot determine at this time when it will generate any significant revenues. As of December 31, 2014, the Company's cash and cash equivalents was approximately $11,434. If existing cash is insufficient to satisfy its liquidity requirements, or if it develops additional products, the Company may seek to sell additional debt or equity securities. If additional funds are raised through the issuance of debt securities, these securities would have rights senior to those associated with the Company's common stock and could contain covenants that would restrict the Company's operations. Any additional financing may not be available in amounts or on terms acceptable to the Company, or at all. If the Company is unable to obtain any additional financing, it may be required to reduce the scope of, delay or eliminate some or all of planned product research development and commercialization activities, which could harm its business.

The Company's financial statements are prepared in accordance with GAAP applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. In addition, as of December 31, 2014, the Company had an accumulated deficit of $182,293, had incurred a net loss for the year ended December 31, 2014, of $14,145 and had positive working capital of $14,517. Funding has been provided by related parties as well as new investors committed to making it possible to maintain, expand, and ensure the advancement of the MelaFind product. The Company has not made any adjustment to the financial statement regarding this uncertainty and continues to report as a going concern.

3. Summary of Significant Accounting Policies

Cash and Cash Equivalents

Cash equivalents primarily represent funds invested in money market funds, bank certificates of deposit and U.S. government debt securities with an original maturity of three months or less at the date of acquisition.

At year end, the Company has maintained bank balances in excess of insurance limits established by the Federal Deposit Insurance Corporation. The Company has not experienced any losses with respect to its placement of cash. Management believes the Company is not exposed to any significant credit risk with respect to its cash and cash equivalents.

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could materially differ from those estimates.

Allowance for Doubtful Accounts

The Company establishes an allowance for uncollectible trade accounts receivable based on the age of outstanding invoices and management's evaluation of collectability of outstanding balances. These provisions are established when the aging of outstanding amounts exceeds allowable terms and are re-evaluated at each quarter end for adequacy. In determining the adequacy of the provision, the Company considers known uncollectible or at risk receivables.

Inventories

Inventories consist of finished products and raw materials that are stated at the lower of cost (first-in, first-out) or market value. As of December 31, 2014 the reserve for obsolete inventory totaled $870. The Company reserves for specific inventory items that are no longer being used in the devices.

Throughout the year, the Company deferred repairs of certain of its MelaFind system units that it determined were unlikely to be sold during the next several periods. The Company estimated the cost to restore its system units to sellable condition and created a repair reserve amounting to $539 at December 31, 2014.

In mid 2013, because the Company's initial launch objectives for the MelaFind system were not met, a significant cost reduction program was put into place and as part of a strategy review, in December 2013; the Company amended its business model from solely a rental-based model to include a capital sales option for the MelaFind device.

Business Segments

The Company's operations are confined to one business segment: the design, development and commercialization of the MelaFind system.

Revenue recognition

The Company considers revenue to be earned when all of the following criteria are met: persuasive evidence a sales arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. The Company's agreements with dermatologists regarding the MelaFind system combine the elements noted above with a future service obligation. In December 2013, the Company changed its business model from solely a rental-based model to include a capital sales option for its MelaFind product. Therefore, the Company will recognize revenues for product sales when title and risk of loss transfer to customers, which occurs upon completion of installation and training on the MelaFind system, when reliable estimates of sales allowances and warranties can be made, and collectability is reasonably assured. The Company will regularly review the information related to these estimates and adjust the reserves accordingly.

The Company also generated revenues from usage, based on the number of patient sessions or lesions examined, or a fixed monthly fee. The Company charges an initial installation fee for each MelaFind system which covers training, delivery, initial supplies, maintenance and the right to use MelaFind. In accordance with the accounting guidance regarding multiple-element arrangements, the Company allocates total contract consideration to each element based upon the relative standalone selling prices of each element, and recognizes the associated revenue for each element as delivery occurs or over the related service period, generally expected to be two years. Revenues associated with undelivered elements are deferred until delivery occurs or services are rendered. The significant judgments the Company makes relate to allocation of the contract consideration to each element whereby changes in standalone selling price could impact the amount of revenue recognized in a specific period and estimates of uncollectible accounts receivables.

In Germany, the typical contract with dermatologists calls for an installation or fixed monthly fee. Additionally, the Company typically charges a per patient usage charge. Revenue generated from German contracts is recognized when earned.

Cost of Revenue

Costs of revenue are associated with the costs of the Melafind system at time of sale and/or the costs to convert from a lease to a sale, warranty costs, repair costs, the placement costs of the MelaFind system in the doctor's office on a lease, the cost of consumables delivered at installation, technical support costs and depreciation expense of the MelaFind system placed with the customer under lease which remains the property of the Company. Also, certain product quality and manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind are allocated to costs of revenue.

Property and Equipment

For the year ended December 31, 2014 and 2013, the Company capitalized approximately $0 and $5,188, respectively of MelaFind system costs. Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the related assets (generally three to five years). Costs incurred for maintenance and repairs are expensed as incurred and expenditures for major replacements and improvements are capitalized and depreciated over their estimated remaining useful lives.

Deferred Financing Costs

Financing costs incurred in connection with the 4% Senior Secured Convertible Debentures were deferred and are being amortized over the term of the debentures using the effective interest rate method. As of December 31, 2014 and 2013 the Company recorded deferred financing costs of $821 and $0, respectively.

Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition does not exceed its carrying amount. The amount of impairment loss, if any, is measured as the difference between the net book value of the asset and its estimated fair value.

Research and Development

Expenditures for research and development are expensed as incurred.

Accrued Expenses

As part of the process of preparing financial statements, management is required to estimate accrued expenses. This process involves identifying services that have been performed and estimating the level of service performed and the associated cost incurred for such service where it has not been invoiced or otherwise notified of the actual cost. Examples of estimated accrued expenses include:

- professional service fees;
- contract clinical and regulatory related service fees;
- fees paid to contract manufacturers in conjunction with the production of MelaFind components or materials; and
- fees paid to third party data collection organizations and investigators in conjunction with the clinical trials and FDA and other regulatory review.

In connection with such service fees, management estimates are most affected by projections of the timing of services provided relative to the actual level of services provided by such service providers. In the event that we do not identify certain costs that have begun to be incurred or we under or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often subjective determinations. The Company makes these judgments based upon the facts and circumstances known and accrues for such costs in accordance with accounting principles generally accepted in the U.S.

Deferred Rent

Operating lease agreements which contain provisions for future rent increases or periods in which rent payments are reduced or abated are recorded in monthly rent expense in the amount of the total payments over the lease term divided by the number of months of the lease term. The difference between rent expense recorded and the amount paid is credited or charged to deferred rent which is reflected on the accompanying balance sheet.

(In thousands, except for share and per share data)

Stock-Based Compensation

The Company records compensation expense associated with employee stock options, restricted stock awards and other forms of equity compensation in accordance with FASB ASC 718, *Compensation-Stock Compensation*. The fair value of an equity award is determined at the date of grant using the Black-Scholes Model and the fair value of the equity award is expensed over the service period. The most significant inputs used to value an equity award include current stock price, the amount the employee must pay to acquire the equity award, volatility rate, interest rate and estimated term. For equity awards that vest upon achieving a defined milestone, the underlying compensation charge is recorded when it is probable that the milestone will be achieved. It is then amortized over the estimated period to satisfy vesting requirements. The probability of vesting is updated at each reporting period and compensation is adjusted accordingly. The significant judgments relate to the assumptions used in the valuation model to determine the fair value of the equity instrument including the volatility rate, term and interest rate. Any increases (decreases) in either of the volatility rate, the term or the interest rate would increase (decrease) the value of the equity instrument and the corresponding compensation expense recognized each period. Estimates of performance based awards vesting can also have a significant impact on recognized stock compensation as the likelihood of a performance based award vesting can change from period-to-period with changes in estimates included in current period operations.

Stock-based compensation to non-employee consultants, accounted for pursuant to FASB ASC 505-50 "*Equity, Equity-Based Payments to Non-Employees",* is granted for services rendered and is completely vested on the grant date. The fair value of the award is determined on the date of grant using the Black-Sholes Model and the fair value is expensed in current period operations.

Income Tax Expense Estimates and Policies

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

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

With respect to uncertain tax positions, the Company would recognize the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the position. The tax benefits to be recognized in the financial statements from such a position would be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. The Company currently has no uncertain tax positions.

The Company does not have any unrecognized tax benefits or accrued penalties and interest. If such matters were to arise, the Company would recognize interest and penalties related to income tax matters in income tax expense. The earliest open tax year subject to examination is 2009.

Net Loss Per Common Share

Basic net loss per common share excludes dilution for potentially dilutive securities and is computed by dividing loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share gives effect to dilutive options, warrants and other potential common shares outstanding during the period. Diluted net loss per common share is equal to the basic net loss per common share since all potentially dilutive securities are anti-dilutive for each of the periods presented. Potential common stock equivalents outstanding as of December 31, 2014 and 2013 consist of the following:

	Year Ended December 31,	
	2014	**2013**
Warrants	13,078,920	1,209,361
Convertible debentures	5,228,465	-
Convertible prefered stock	4,595,321	-
Common stock options	1,308,835	306,616
Restricted stock Awards	-	9,941
Total	24,211,541	1,525,918

Comprehensive loss

For all periods presented, the Company had no comprehensive income items and accordingly there is no difference between the reported net loss and per share amounts per the Statements of Operations and comprehensive net loss and related per share amounts.

Litigation

From time to time, the Company may become involved in litigation and other legal actions. The Company estimates the range of liability related to any pending litigation where the amount and range of loss can be estimated. The Company records its best estimate of a loss when the loss is considered probable. Where a liability is probable and there is a range of estimated loss with no best estimate in the range, the Company records a charge equal to at least the minimum estimated liability for a loss contingency when both of the following conditions are met: (i) information available prior to issuance of the financial statements indicates that it is probable that a liability had been incurred at the date of the financial statements and (ii) the range of loss can be reasonably estimated. Through the date of these financial statements, the Company is not involved in litigation or other legal actions.

Fair Value Measurements

The Company has adopted the provisions of FASB ASC Topic 820, "Fair Value Measurements and Disclosures" as of January 1, 2008 for financial instruments. This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. ASC 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. ASC 820 permits an entity to measure certain financial assets and financial liabilities at fair value with changes in fair value recognized in earnings each period.

Warrant Liability

The Company accounts for the 685,715 common stock warrants issued in connection with the October 31, 2013 financing and 1,329,731 common stock warrants issued in connection with the February 2014 financing in accordance with the guidance contained in ASC 815-40-15-7D, "Contracts in Entity's Own Equity" whereby under that provision they do not meet the criteria for equity treatment and must be recorded as a liability. Accordingly, the Company classifies the warrant instrument as a liability at its fair value and adjusts the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's statements of operations. The fair value of the warrants issued by the Company in connection with the financing transactions has been estimated using the Black-Scholes valuation model. The Black-Scholes valuation model was deemed appropriate given the terms of the warrants, and the fact that the key inputs do not change throughout the life of the warrants.

Recently Issued Accounting Standards

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update "ASU" No. 2014-15 on "*Presentation of Financial Statements Going Concern (Subtopic 205-40)* – Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". Currently, there is no guidance in U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in this update provide that guidance. In doing so, the amendments are intended to reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this update are effective for annual periods ending after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the new guidance to determine the impact the adoption of this guidance will have on the Company's results of operations, cash flows or financial condition.

In May 2014, the FASB issued ASU No. 2014-09, "*Revenue from Contracts with Customers (Topic 606)*." ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. ASU 2014-09 is effective for public entities for annual reporting periods beginning after December 15, 2016 and interim periods within those periods. Early adoption is not permitted. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements and footnote disclosures.

(In thousands, except for share and per share data)

Foreign Exchange

The Company's operations in Germany use the U.S. dollar as its functional currency and from time to time conducts business in Euros. For all periods presented, aggregate foreign exchange transaction gains and losses were not material.

4. Inventory

Inventories currently consist of MelaFind systems; work in process components and other finished products and accessories that are stated at the lower of cost or market value. Inventory accessories are purchased items to be sold for use in the operation of the MelaFind systems. The Company maintains a reserve for specific inventory items that are no longer being used in the devices.

During the third quarter of 2014, the Company replaced the Hand-held Imager's "Field Phantom" imaging test with the "Flap Shutter" imaging test. The new Flap Shutter test utilizes an internal imaging target within each Hand-held Imager. This new test process eliminates the need for the external Field Phantom imaging test fixture; thereby reducing manufacturing material costs, test labor and cycle time. As a result, the Phantom Fixture has become obsolete and $545 was added to the reserve for obsolete inventory.

On August 6, 2014, the Company and Askion GmbH entered into an "Amended and Restated Askion Production Agreement." This agreement is a mutual settlement and release agreement of two prior unfulfilled purchase orders. The settlement amount of $1,143 was used for inventory purchases which consist primarily of Hand-held Imager assemblies and raw materials.

Throughout 2014, the Company deferred repairs of certain of its MelaFind system units that it determined were unlikely to be sold during the next several periods. The Company estimated the cost to restore its system units to sellable condition and created a repair reserve amounting to $539 at December 31, 2014.

In December 2013, the Company amended its business model for the MelaFind system from solely a rental-based model to include a capital sales option. In accordance with this new model, the Company reclassified $5,402 of MelaFind systems from property and equipment into inventory at December 31, 2013. The systems reclassified into inventory represent systems available for sale.

Inventory consists of the following:

	December 31,	
	2014	**2013**
MelaFind Systems	$ 3,268	$ 5,402
Hand-held Imager assemblies	350	-
Components/raw materials	2,552	-
Accessories	514	554
	6,684	5,956
Reserve for obsolete inventory	(870)	(325)
Reserve for inventory repairs	(539)	-
	$ 5,275	$ 5,631

5. Property and Equipment

In December 2013, the Company amended its business model for the MelaFind system from solely a rental-based to include a capital sales option. In accordance with this new sales model, the Company reclassified $5,402 of MelaFind systems from property and equipment into inventory at December 31, 2013. The systems reclassified into inventory represent systems available for sale. Systems that have been leased under the rental-based model remain in property and equipment.

During the year ended December 31, 2014, the Company reclassified $726 of accumulated depreciation related to MelaFind system components that were previously leased and are now available for sale that were included in inventory at December 31, 2013.

(In thousands, except for share and per share data)

Property and equipment, at cost, consists of the following:

	December 31,		Estimated	
	2014	2013	Useful Life	Useful Life
Leasehold improvements	$ 906	$ 906	Lease Term	Lease Term
Laboratory and research equipment	1,084	1,084	3-5 years	3-5 years
Office furniture and equipment	1,969	2,023	3-5 years	3-5 years
MelaFind Systems	3,194	5,081	3 years	3 years
	7,153	9,094		
Accumulated depreciation and amortization	(5,192)	(5,403)		
	$ 1,961	$ 3,691		

Depreciation expense amounted to approximately $1,785 and $2,434 for the years ended December 31, 2014 and 2013, respectively.

6. Patents and trademarks

Patents and trademarks as shown in the accompanying balance sheets are net of accumulated amortization of $237 and $232 at December 31, 2014 and 2013, respectively. Amortization expense related to all patents was approximately $5 and $5 for the years ended December 31, 2014 and 2013, respectively. Amortization expense of currently held patents is expected to amount to $5 for each of the years ending December 31, 2015 through 2019, respectively.

7. Commitments and Contingencies

The Company is obligated under a non-cancelable operating lease for office, lab, and manufacturing space expiring December 2016. The lease is subject to escalations for increases in operating expenses. For the years ended December 31, the approximate aggregate minimum future payments due under this lease are as follows:

2015	$ 478
2016	477
TOTAL	$ 955

Rent expense charged to operations amounted to approximately $445 and $509 for the years ended December 31, 2014 and 2013, respectively.

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

8. Employee Benefit Plan

In November 2014, the Company adopted a 401K plan for the benefit of the employees. The Company did not make any contributions to the plan for the year ended December 31, 2014.

In 2013 and prior, the Company had a SIMPLE IRA defined contribution plan covering all qualified employees. An officer of the Company served as trustee of the plan. The Company provided a matching contribution of up to 3% of each employee's salary. Company contributions to this plan amounted to approximately $136 for the year ended December 31, 2013. On December 31, 2013 the Company ceased contributions and terminated the plan.

9. Debt

On July 21, 2014, the Company entered into a definitive Securities Purchase Agreement (the "Purchase Agreement") with entities affiliated with institutional investors (the "Investors") providing for the issuance of Senior Secured Convertible Debentures in the aggregate principal amount of $15,000, due, subject to the terms therein, in July 2019 (the "Debentures"), and warrants (the "July 2014 Series A Warrants") to purchase up to an aggregate of 6,198,832 shares of common stock, $0.001 par value per share, at an exercise price of $2.45 per share expiring in July 2019. The Debentures bear interest at an annual rate of 4%, payable quarterly or upon conversion into shares of common stock. The Debentures are convertible at any time into an aggregate of 5,847,955 shares of common stock at an initial conversion price of $2.565 per share (which represents a price above the closing bid price of the common stock on July 18, 2014, the trading day immediately prior to the entry into the Purchase Agreement). The Company's obligations under the Debentures are secured by a first priority lien on all of the Company's intellectual property pursuant to the terms of a security agreement ("Security Agreement") dated July 21, 2014 among the Company and the investors. In connection with the Purchase Agreement, the Company entered into a Registration Rights Agreement with the Investors pursuant to which the Company was obligated to file a registration statement to register for resale the shares of common stock issuable upon conversion of the Series B Preferred Stock and Debentures and upon exercise of the Warrants. Under the terms of the Registration Rights Agreement, the Company filed a registration statement on August 19, 2014, which was declared effective by the SEC on October 20, 2014 (File No. 333-198249). Proceeds from the Debentures are being used for general working capital purposes.

Additionally, in connection with the Purchase Agreement the Company exchanged with certain investors, 12,300 shares of Series A convertible preferred stock issued on February 5, 2014 for 12,300 shares of Series B convertible preferred stock, par value $0.10 and a stated value of $1,000 per share (the "Series B Preferred Stock"), and warrants (the "July 2014 Series B Warrants") to purchase up to an aggregate of 4,795,321 shares of common stock at an exercise price of $2.45 per share expiring in January 2016. The offering closed on July 24, 2014.

For financial reporting purposes, the $15,000 gross proceeds of the Debentures, was allocated first to the fair value of the obligation to issue the warrants, which totaled $5,296, then to the intrinsic value of the beneficial conversion feature on the Debentures of $4,566.The balance was further reduced by the fair value of warrants issued to the placement agent for services rendered of $491, resulting in an initial carrying value of the Debentures of $4,647. The initial debt discount on the Debentures totaled $10,353 and will be amortized over the five year life of the Debentures. The Company used a Level 3 fair value measurement to determine fair value of the warrant obligations, which has significant unobservable inputs as defined in Accounting Standards Codification 820 "Fair Value Measures". The fair value of the warrant obligation was determined using an option pricing model that used various assumptions including: a stock price of $2.44 per share, volatility of 93.46%, time to maturity of 5.0 years, exercise price of $2.45 per share and a risk free rate of return of 1.62%.

On October 22, 2014, $1,589 worth of Debentures was converted into 619,490 shares of common stock. The resulting debt discount and deferred financing cost adjustment resulted in accelerated interest expense of approximately $1,200.

On March 15, 2013, the Company executed loan documents with Hercules Technology Growth Capital Inc., a venture capital lender, whereby the Company borrowed $6,000 ("Loan"). The Loan accrued interest at a rate of 10.45%. The term of the Loan was 42 months with interest payments only during the first 12 months. On September 10, 2013, the Company elected to prepay the Loan and paid Hercules approximately $6,400, including the end of term fee of $425, to settle all obligations to Hercules. Hercules agreed to waive the prepayment penalty that was defined in the loan documents.

Upon executing the loan documents on March 15, 2013 the Company became obligated to issue to the Lender a warrant to purchase shares of the Company's common stock upon approval by the Company's stockholders of a proposal to increase the Company's number of authorized shares of common stock at its 2013 Annual Meeting of Stockholders. The Company's stockholders approved the increase in the number of authorized shares of common stock on April 25, 2013 and on April 26, 2013 the warrant was issued to the Lender. Accordingly, the Lender received a warrant to purchase 69,321 shares of common stock at an exercise price of approximately $11.18 per share. This warrant will expire on April 26, 2018.

For financial reporting purposes, the $6,000 funded by the Lender on March 15, 2013 was allocated first to the fair value the warrant that totaled approximately $563 and the balance was reduced further by the Lender's costs and fees, resulting in an initial carrying value of the loan of approximately $5,300. The Company used a Level 3 fair value measurement to determine fair value of the warrant obligation, which has significant unobservable inputs as defined in Accounting Standards Codification 820 "Fair Value Measures". During the period from the loan inception date until the warrant obligation was fulfilled and the warrant was issued, the warrant obligation was reflected as a long-term liability at fair value. Changes in the fair value ("mark-to-market adjustments") of the warrant obligation of approximately $90 are included in operating results. The fair value of the warrant obligation was determined using the Monte Carlo pricing model that used various assumptions that included: stock prices ranging from $11.60 to $11.80 per share, volatility of 77%, time to maturity of 5 years, exercise prices ranging from $11.50 to $11.60 and a risk free interest rate of return of .84%. Under the Monte Carlo model, a 10% change in the underlying unobservable inputs would not have a significant impact on the fair value.

The value of the warrant obligation combined with the costs resulted in an initial loan discount of approximately $727. The terms of the Loan included a back-end fee of $425 payable at the maturity of the Loan . The loan discount and the fee were being amortized as additional interest expense over the life of the loan using the interest method. As discussed above, prior to the terms of the warrant being fixed on April 26, 2013, the warrant obligation fell within the scope of Accounting Standards Codification 815 "Derivatives and Hedging" ("ASC 815") and therefore the warrant obligation was accounted for as a derivative reflected as a long-term liability until the warrant was issued on April 26, 2013. The terms of the warrant upon issuance no longer required derivative accounting under ASC 815 and therefore the fair value of the warrant at that date was classified within stockholders equity.

(In thousands, except for share and per share data)

Upon repayment of the loan in September 2013, the Company recognized the balance of the unamortized loan discount, fee and deferred financing costs of approximately $983.

10. Recurring Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value for applicable assets and liabilities, we consider the principal or most advantageous market in which we would transact and we consider assumptions market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. This guidance also establishes a fair value hierarchy to prioritize inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company's financial instruments are cash and cash equivalents, accounts receivable, accounts payable, senior secured convertible debentures and derivative warrant liabilities. The recorded values of cash equivalents, accounts receivable and accounts payable approximate their fair values based on their short-term nature. The fair value of derivative warrant liabilities is estimated using option pricing models that are based on the individual characteristics of our warrants, preferred and common stock, the derivative warrant liability on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate and, in some cases, credit spread. The derivative warrant liabilities are the only recurring Level 3 fair value measures.

A summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy as of December 31, 2014 and December 31, 2013 is as follows:

Black-Scholes Warrant Pricing	**December 31, 2014**	**December 31, 2013**
Stock Price	$ 1.20	$ 6.40
Risk-free Rate (5-year U.S. Treasury Yield)	1.65%	1.75%
Volatility (Annual)	72.90-88.10%	93.43%
Time to Maturity (Years)	4.10-4.33	5.33

(In thousands, except for share and per share data)

At December 31, 2014 and December 31, 2013, the estimated fair values of the liabilities measured on a recurring basis are as follows:

	Fair Value Measurements at December 31, 2014			
	Balance at December 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant derivative liabilities	$ 499	$ —	$ —	$ 499
Total	$ 499	$ —	$ —	$ 499

	Fair Value Measurements at December 31, 2013			
	Balance at December 31, 2013	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant derivative liabilities	$ 3,017	$ —	$ —	$ 3,017
Total	$ 3,017	$ —	$ —	$ 3,017

The following tables present the activity for liabilities measured at estimated fair value using unobservable inputs for the years ended December 31, 2014 and 2013:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
	Warrant Derivative Liabilities
Beginning Balance at January 1, 2013	$ -
Issuance of warrants classified as derivative liabilities	3,373
Changes in estimated fair value	296
Reclassification of derivative liability to additional paid-in capital	(652)
Ending balance at December 31, 2013	$ 3,017
Issuance of warrants classified as derivative liabilities	5,585
Changes in estimated fair value	(8,103)
Ending balance at December 31, 2014	$ 499

Reclassification of derivative liability to additional paid-in capital relates to the warrants issued in connection with the debt financing that occurred on March 15, 2013. These warrants were accounted for as a liability until such time as the stockholders of the Company approved an increase in the number of authorized shares of the Company's common stock.

11. Reverse Split of Common Stock

On July 9, 2014, the Company affected a previously authorized 1-for-10 reverse stock split of its common stock. The reverse split took effect at the start of trading on July 10, 2014 on a 1-for-10 split basis. All prior periods have been retroactively adjusted to reflect the reverse stock split. The par value of the common stock did not change.

12. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock with a par value of $0.10 per share with such designation rights and preferences as may be determined from time to time by the Company's board of directors. There were 11,787 shares and 0 shares of preferred stock issued and outstanding on December 31, 2014 and December 31, 2013, respectively.

On July 24, 2014, in connection with the offering (see Note 9 "Debt"), the Company exchanged 12,300 shares of its Series A convertible preferred stock issued on February 5, 2014 with 12,300 shares of Series B convertible preferred Stock at a stated value of $1,000 per share convertible into common stock at an initial price of $2.565 per share and July 2014 Series B Warrants to purchase up to an aggregate of 4,795,321 shares of common stock at an exercise price of $2.45 per share, expiring in January 2016. The preferred stock is convertible into an aggregate of 4,795,321 shares of common stock. Holders of the preferred stock are entitled to dividends only in the event that dividends are paid on the common stock, and the preferred stock has no preferences over the common stock, including liquidation rights. The Series B Preferred Stock and the July 2014 Series B Warrants are immediately exercisable and are subject to certain ownership limitations.

For financial reporting purposes, the $12,300 preferred stock value was allocated first to the fair value of the July 2014 Series B warrants, which totaled $2,487, then to the intrinsic value of the beneficial conversion feature of $1,887. The amount of the beneficial conversion feature is considered to be a deemed dividend on the date of issuance to the Series B preferred stockholders due to the July 2014 Series B Warrants being immediately exercisable.

On February 5, 2014, pursuant to a securities purchase agreement, dated as of January 31, 2014, the Company sold to the Purchasers (i) an aggregate of 12,300 shares of Series A Convertible Preferred Stock, par value $0.10 and a stated value of $1,000 per share (the "Series A Preferred Stock"), convertible into 1,464,287 shares of common stock at an initial conversion price of $8.40, and (ii)warrants to purchase up to 1,329,731 shares of common stock for net proceeds of $11,458. The warrants have an exercise price of $7.40 per share, are immediately exercisable and have a term of five years. These warrants have non-standard terms as they relate to a fundamental transaction and require a net-cash settlement upon a change in control of the Company and therefore are classified as a derivative liability and recorded at fair value on the inception date of February 5, 2014. They will be recorded at their respective fair value at each subsequent balance sheet date. The fair value of these warrants on December 31, 2014, was approximately $266. The change in fair value of these warrants for the twelve months ended December 30, 2014 was a benefit of $5,319 (see Note 10 "Fair Value of Financial Instruments").

Pursuant to the terms of the Purchase Agreement, the Series A Convertible Preferred Stock was exchanged for the Series B Convertible Preferred Stock. In September 2014, the Company amended the registration statement related to the Series A Convertible Preferred Stock to deregister those shares that would have been issuable upon conversion of the Series A Convertible Preferred Stock had it not already been redeemed by the proceeds of the Series B Convertible Preferred Stock.

In connection with this financing, the Company also granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Series A Preferred Stock and the warrants pursuant to the terms of a Registration Rights Agreement. The Purchasers were entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, effectiveness and maintaining an effective registration statement covering the shares underlying the Series A Preferred Stock and the warrants. The Company was unable to meet certain filing and effectiveness requirements and as a result paid liquidated damages to the Purchasers in the aggregate amount of $3,420.

Common Stock and Warrants

The Company is authorized to issue 50,000,000 shares of common stock with a par value of $0.001 per share. There were 6,037,232 and 4,750,160 shares of common stock issued and outstanding at December 31, 2014 and December 31, 2013, respectively.

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

The October 2013 Series A Warrants have non-standard terms as they relate to a fundamental transaction and require a net-cash settlement upon a change in control of the Company and therefore are classified as a derivative. These warrants have been recorded at fair value at the inception date and will be recorded at their respective fair values at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge in the Statements of Operations. The fair value of these warrants on December 31, 2014 and December 31, 2013 was approximately $233 and $3,017, respectively. The change in fair value of these warrants for the twelve months ended December 31, 2014 and 2013, was a benefit of $2,784 and charge of $206, respectively (see Note 10 "Fair Value of Financial Instruments").

(In thousands, except for share and per share data)

Outstanding common stock warrants on December 31, 2014 consist of the following:

Issue Date	Expiration Date	Total Warrants	Ex. Price
4/26/2013	4/26/2018	69,321	$ 11.18
10/31/2013	4/30/2019	685,715	$ 8.50
2/5/2014	2/5/2019	1,329,731	$ 7.40
7/24/2014	7/24/2019	6,198,832	$ 2.45
7/24/2014	1/24/2016	4,795,321	$ 2.45
		13,078,920	

On August 22, 2013, the Company received a notice from NASDAQ that, for the previous 30 consecutive business days, the Company was not in compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Capital Market. In July 2014, the Company effected a one-for-ten reverse split of its common stock in order to regain compliance with the minimum bid price requirement prior to the expiration of the last applicable grace period. On July 24, 2014, the Company was notified by NASDAQ that it is now in compliance with the minimum bid price requirement.

13. Stock-Based Compensation

Stock Options

On April 25, 2013, the Company's stockholders approved the Company's adoption of the new 2013 Stock Incentive Plan ("2013 Plan") having 3,500,000 shares available for issuance in respect of awards made thereunder. The Company terminated the 2005 Stock Incentive Plan in December 2014. As of December 31, 2014, the aggregate number of shares of common stock remaining available for issuance for awards under the 2013 Plan totaled 2,301,691.

Stock awards under the Company's stock option plans have been granted with exercise prices which are no less than the market value of the stock on the date of the grant. Options granted under the 2013 and 2005 Plans are generally time-based or performance-based options and vesting varies accordingly. Options under the plans expire up to a maximum of ten years from the date of grant. Compensation expense recognized in the Statement of Operations during 2014 and 2013 for stock options and restricted stock awards amounted to $413 and $1,301, respectively. Cash received from options exercised under all share-based payment arrangements for the year ended December 31, 2013 was $18, there were no exercises in 2014.

The fair value of each option award granted is estimated on the date of grant using the Black-Scholes option valuation and assumptions as noted in the following table:

	December 31, 2014	December 31, 2013
Expected life	5-10 years	5-10 years
Expected volatility	74-83%	72-77%
Risk-free interest rate	1.90-2.45%	0.71-2.45%
Dividend yield	-	-

The expected life of the options is based on the observed and expected time to full-vesting, forfeiture and exercise. Groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. The expected volatility assumptions were determined based upon the historical volatility of the Company's daily closing stock price. The risk-free rate is based on rates provided by the U.S. Treasury with a term equal to the expected life of the option. The Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

At December 31, 2014, stock options to purchase 1,308,835 shares of common stock at exercise prices ranging from $1.31 to $68.90 per share are outstanding and are exercisable at various dates through 2024. The total number of options exercisable at December 31, 2014 and 2013 was 101,376 and 126,183 respectively, with weighted average exercise prices of $13.45 and $25.60, respectively.

(In thousands, except for share and per share data)

The status of the Company's stock option plans during the periods indicated is summarized as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2012	242,654	$ 40.10	7.0	$ 29
Granted	499,447	14.60	9.5	-
Exercised	(1,806)	10.00		17
Forfeited or expired	(433,679)	27.70		27
Outstanding at December 31, 2013	306,616	16.20	9.0	
Granted	1,205,162	1.70	9.4	
Exercised	-	-		
Forfeited or expired	(202,943)	16.74		
Outstanding at December 31, 2014	1,308,835	2.76	9.8	
Vested and exercisable at December 31, 2014	101,376	$ 13.45	8.4	$ -

During the years ended December 31, 2014 and 2013 the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was $1.22 and $6.00 per share, respectively. The total intrinsic value of options exercised during the year ended December 31, 2013 $17, there were no exercises in 2014. The requisite service periods for options granted during 2014 and 2013 for employees was four years and for directors was one year.

The following table summarizes information about stock options outstanding at December 31, 2014:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	**Number Outstanding**	**Weighted-Average Remaining Contractual Life**	**Weighted-Average Exercise Price**	**Number Exercisable**	**Weighted-Average Exercise Price**
$.01-$3.00	1,125,000	9.95 years	$ 1.40	-	$ -
$3.01-$10.00	147,553	8.98 years	6.95	70,443	7.51
$10.01-$70.00	36,282	7.41 years	27.89	30,933	26.97
$.01-$70.00	1,308,835	9.77 years	$ 2.76	101,376	$ 13.45

As of December 31, 2014, of the total 1,308,835 options outstanding, 1,207,459 have not vested. Of this total unvested amount, 392,425 will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. There was $1,293 of total unrecognized compensation cost related to unvested options, of which approximately $392 will be recognized upon achievement of performance milestones and $901 upon completion of the requisite service period. On February 11, 2013, the Company's former chief executive officer contractually agreed to not exercise 90,000 fully vested options until such time as the stockholders of the Company approved an increase in the number of authorized shares of the Company's common stock, or, if earlier, the Company's written consent. On April 25, 2013, the Company's stockholders approved an increase in the authorized shares of common stock and therefore the restriction placed on the former CEO's ability to exercise the 90,000 fully vested options lapsed. For financial reporting purposes, the Forbearance Agreement was accounted for at the time it was executed as a cancellation with no concurrent grant and therefore upon the lapsing of the exercise restriction on April 25, 2013, the Company recognized additional stock compensation of approximately $423.

14. Other Income

In 2005, the Company discontinued all operations associated with its DIFOTI product. Under an exclusive sale and licensing agreement with KaVo Dental GmbH ("KaVo") to further develop and commercialize DIFOTI, KaVo pays the Company an annual royalty based on the number of DIFOTI related systems sold per calendar year. Other income includes approximately $149 and $20 in royalty income in the years ended December 31, 2014 and 2013, respectively.

15. Related Party Agreements

Gravitas Healthcare LLC

Mr. Samuel E. Navarro, a member of the Company's Board of Directors and managing partner of Gravitas Healthcare LLC, received $86 of a placement fee paid by the Company to Gravitas for services rendered in connection with the sale of the Company's Series A Convertible Preferred Stock completed in February 2014.

Transition Services Provided by Robert Coradini

On March 11, 2014, the Company agreed to pay Robert Coradini, a director and the Company's former Interim Chief Executive Officer, approximately $48 in consideration for services provided in connection with the transition to a new Chief Executive Officer during the fourth quarter of 2013.

(In thousands, except for share and per share data)

16. Income Taxes

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

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

The Company has incurred net losses since inception, accordingly, it has not provided for income taxes for the years ended December 31, 2014 and 2013.

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

	For the years ended December 31,	
	2014	2013
Computed expected tax benefit	$ (4,270)	$ (8,822)
State tax benefit, net of federal effect	(217)	(1,557)
Increase in the valuation allowance	4,487	10,379
Provision for income taxes	$ -	$ -

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities as of December 31, 2014 and 2013 are as follows:

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforward	$ 57,367	$ 35,086
Capitalized research and developmental costs	12,925	27,794
Inventory	689	-
Reserves & accrued expenses	135	-
Warrant Liability	(3,123)	-
Property & equipment	(785)	-
Non-cash compensation	3,840	3,681
Total deferred tax assets	71,048	66,561
Less valuation allowance	(71,048)	(66,561)
Net deferred tax assets	$ -	$ -

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based on the Company's historical net losses, management does not believe that it is more-likely-than not that the Company will realize the benefits of these deferred tax assets and, accordingly, a full valuation allowance has been recorded against the deferred tax assets as of December 31, 2014 and 2013. The Company's valuation allowance against its deferred tax assets increased by $4,487 and $10,379 for the years ended December 31, 2014 and 2013, respectively.

At December 31, 2014, the Company has federal net operating loss carryforwards of approximately $144,759 to offset future taxable income. The Company has experienced certain ownership changes which, under the provisions of Section 382 of the Internal Revenue Code of 1986, as amended, result in annual limitations on the Company's ability to utilize its net operating losses in the future. The February 2014 and July 2014 equity raises by the Company, will likely limit the annual use of these net operating loss carryforwards.

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

The Company does not have any unrecognized tax benefits or accrued penalties and interest. If such matters were to arise, the Company would recognize interest and penalties related to income tax matters in income tax expense. The earliest open tax year subject to examination is 2010.

17. Restructuring Charge

As discussed in Note 1, in response to recurring operating losses and limited liquidity, the Company's Board of Directors approved the Cost Reduction Plan that included a reduction in work force, the prospective elimination or deferral of all nonessential projects and activities and the scaling back or discontinuance of general corporate activities. The communication to affected employees was made during August 2013. In connection therewith, the Company recorded a charge for employee termination benefits totaling approximately $100 in the third quarter of 2013 that is reflected in the statement of operations as increases in cost of revenue, research and development and selling, general and administrative expenses. As of December 31, 2014 substantially all termination benefits have been paid.

18. Subsequent Event

Subsequent to year end and through the date of this filing, $2,308 worth of the Company's Debentures were converted into 899,999 shares of common stock and $1,508 worth of Series B convertible preferred stock were converted into 587,915 shares of common stock.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Evaluation of disclosure controls and procedures

We completed an evaluation, as of December 31, 2014, under the supervision of and with participation from management, including the chief executive officer and chief financial officer, as to the effectiveness of the design and operation of our disclosure controls and procedures. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company's disclosure controls and procedures as of December 31, 2014, the chief executive officer and the chief financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level at that date. Management has identified and implemented certain remediatory procedures, including a more rigorous and timely quarterly closing process designed to permit adequate review time that is intended to reasonably assure management that our disclosure controls and procedures are effective. Upon completion of the closing process following the end of the first quarter of 2015, management will determine whether the material weakness cited at December 31, 2014 has been remediated.

Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter and year ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

Report of Management on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. Under the rules of the SEC, "internal control over financial reporting procedures" is defined as a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Internal control over financial reporting includes maintaining records, that in reasonable detail, accurately and fairly reflect our transactions and our dispositions of assets; provide reasonable assurance that transactions are recorded as necessary for preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America; provide reasonable assurance that receipts and expenditures of company assets are made only in accordance with management authorization; and provide reasonable assurance regarding the prevention or the timely detection of the unauthorized acquisition, use or disposition of company assets that could have a material effect on our financial statements. Because of its inherent limitations, internal control over financial reporting may not provide absolute assurance that a misstatement of our financial statements would be prevented or detected.

In early 2014, we changed our business model from solely a leased-based model to include a capital sales option and, accordingly, at December 31, 2013, we reclassified a portion of our MelaFind parts, components and systems from fixed assets to inventory. In connection with the audit of our financial statements for the year ended December 31, 2014, management noted that the two accounts impacted by the changes in our business model, inventory and fixed assets, took longer than anticipated to reconcile. Further, an unusually large number of transactions involving fixed assets and inventory occurred at the end of December 2014 due primarily to the Company's increased sales and lease return activities which needed further accounting review and analysis. As a result of these factors, the closing process was delayed and there were a number of post-closing adjustments in these and other areas. Management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by COSO in *Internal Control — Integrated Framework (1992)* and concluded that our internal controls specifically related to proper review and monitoring were not operating effectively at December 31, 2014.

Since December 31, 2014, all accounts have been reconciled appropriately. Management has updated our quarterly closing procedures and implemented a timeline by which to actively monitor our progress with respect to the quarterly close, specifically to permit adequate review. Upon completion of the closing process following the end of the first quarter of 2015 management will determine whether the material weakness cited at December 31, 2014 has been remediated.

Item 9B. ***Other Information***

The following disclosure is made in lieu of filing a Current Report on Form 8-K, Item 2.05, Costs Associated with Exit or Disposal Activities:

On March 26, 2015, we committed to implement a plan of termination that resulted in a workforce reduction of nine employees in order to reduce operating costs. We commenced notification of employees affected by the workforce reduction on March 26, 2015. The workforce reduction is expected to be completed by April 1, 2015, which is the termination date for all of the affected employees.

As a result of the workforce reduction, we estimate that we will record severance-related charges of approximately $110,000, which estimate assumes each affected employee enters into a separation agreement with us. Substantially all of the severance-related charges are expected to be paid during the second quarter of 2015. Severance-related charges that we expect to incur in connection with the workforce reduction are subject to a number of assumptions, including as set forth above, and actual results may differ. We may also incur other charges not currently contemplated due to events that may occur as a result of, or associated with, the plan of termination.

PART III

Item 10. ***Directors, Executive Officers, and Corporate Governance***

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the 2015 Annual Meeting of our Stockholders (the "Proxy Statement"), which is expected to be filed no later than 120 days after the end of our fiscal year ended December 31, 2014, and is incorporated in this report by reference.

Item 11. ***Executive Compensation***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. ***Principal Accountant Fees and Services***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) *Exhibits and Financial Statement Schedules:*

(1) *Financial Statements*

See the "Index to Financial Statements" in Part II Item 8 of this report.

(2) *Financial Statement Schedules*

Not applicable.

(3) *Exhibits*

A list of exhibits required by Item 601 of Regulation S-K filed or incorporated by reference is found in the Exhibit Index immediately following Part IV of this report.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.1	Fifth Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to the Registrant's Registration Statement on Form S-3 (File No. 333-167113) filed on May 26, 2010).
3.2	Third Amended and Restated Bylaws of the Registrant (Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on August 8, 2005).
3.3	Certificate of Amendment to Certificate of Incorporation (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 filed on August 7, 2013).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 3, 2014).
3.5	Certificate of Amendment to Certificate of Incorporation (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 10, 2014).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 23, 2014).
4.1	Specimen Stock Certificate Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on August 8, 2005).
4.2	Warrant dated May 7, 2009 issued by Electro-Optical Sciences, Inc. to Kingsbridge Capital Limited (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on May 8, 2009).
4.3	Warrant Agreement, dated as of April 26, 2013, by and between MELA Sciences, Inc. and Hercules Technology Growth Capital, Inc. (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 filed on April 30, 2013).
4.4	Form of Series A Warrant (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on October 30, 2013).
4.5	Form of Series B Prefunded Warrant (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on October 30, 2013).
4.6	Form of Common Stock Purchase Warrant (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 3, 2014).
4.7	Form of Series [A/B] Common Stock Purchase Warrant (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 23, 2014).
4.8	Form of 4% Senior Secured Convertible Debenture Due July 24, 2019 (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 23, 2014).
10.1*	Form of Indemnification Agreement for directors and executive officers. (Incorporated by reference to Registrant's Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 17, 2014).
10.2*	2005 Stock Incentive Plan (Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), filed on August 8, 2005.
10.3*#	Employment Agreement dated as of December 15, 2015 between Michael R. Stewart and MELA Sciences, Inc. (filed herewith)..
10.4*#	General Release and Severance Agreement dated as of November 17, 2015 between Rose Crane and MELA Sciences, Inc.
10.5*	Employment Agreement, dated April 4, 2014, between Robert W. Cook and MELA Sciences, Inc. (Incorporated by reference to Registrant's Current Report on Form 8-K filed on April 9, 2014).
10.6	Licensing Agreement between the Registrant and KaVo Dental GmbH, dated as of December 5, 2006. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 11, 2006).
10.7	Securities Purchase Agreement dated as of July 21, 2014 between MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 14, 2014).

Exhibit Number	Exhibit Title
10.8	Registration Rights Agreement dated as of July 21, 2014 between MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 14, 2014).
10.9	Security Agreement dated as of July 21, 2014 among MELA Sciences, Inc., all of the Subsidiaries of the Registrant and the holders of the Registrant's 4% Senior Secured Convertible Debentures (Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 14, 2014).
10.10	Agreement of Lease, dated as of July 14, 2009, by and between Stanford Bridge LLC and Electro-Optical Sciences, Inc. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 14, 2009).
10.11	Supply Agreement with Arrow Electronics, Inc., dated April 8, 2011 (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011 filed on August 5, 2011).+
10.12	Production Agreement, dated as of January 6, 2012, by and between MELA Sciences, Inc. and Askion GmbH (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 filed on May 3, 2012).+
10.13	Service Agreement, dated March 21, 2012, by and between MELA Sciences, Inc. and QUINTILES Commercial Germany GmbH (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 filed on May 3, 2012).
10.14	Intentionally omitted.
10.15	Intentionally omitted.
10.16*	MELA Sciences, Inc. 2013 Stock Incentive Plan (Incorporated by reference to the Registrant's Proxy Statement on Schedule 14A filed on March 20, 2013).
10.17	Loan and Security Agreement, dated as of March 15, 2013, by and between MELA Sciences, Inc. and Hercules Technology Growth Capital, Inc. (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 filed on April 30, 2013).
10.18	Intentionally omitted.
10.19	Form of Securities Purchase Agreement, dated as of October 29, 2013, by and among MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on October 30, 2013).
10.20	Intentionally omitted.
10.21	Form of Securities Purchase Agreement, dated as of January 31, 2014, by and among MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 3, 2014).
10.22	Form of Registration Rights Agreement, dated as of February 5, 2014, by and among MELA Sciences, Inc. and the purchasers identified on the signature pages thereto (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 3, 2014).
10.23	Engagement Letter Agreement by and between the Company and H.C. Wainwright & Co. LLC, dated June 13, 2014 (Incorporated by reference to Registrant's Form S-3 registration statement filed on August 19, 2014).
23.1#	Consent of EisnerAmper LLP
31.1#	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101#	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2014 formatted in Extensible Business Reporting Language (XBRL): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Stockholders' Equity (iv) the Statements of Cash Flows, and (v) the Notes to Financial Statements.

* Indicates management compensatory plan, contract or arrangement
Filed herewith
+ Portions of this agreement have been omitted pursuant to a request for confidential treatment.

SIGNATURES

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

MELA SCIENCES, INC.

By: /s/ Michael R. Stewart
Michael R. Stewart
President and Chief Executive Officer
(Principal Executive Officer)

Dated: March 30, 2015

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

Signature	Title	Date
/s/ Michael R. Stewart **Michael R. Stewart**	President and Chief Executive Officer (Principal Executive Officer)	March 30, 2015
/s/ Robert W. Cook **Robert W. Cook**	Chief Financial Officer (Principal Financial Officer)	March 30, 2015
/s/ Jeffrey O'Donnell **Jeffrey O'Donnell**	Director	March 30, 2015
/s/ Samuel E. Navarro **Samuel E. Navarro**	Director	March 30, 2015
/s/ Kathryn Swintek **Kathryn Swintek**	Director	March 30, 2015
/s/ David K. Stone **David K. Stone**	Director	March 30, 2015
/s/ LuAnn Via **LuAnn Via**	Director	March 30, 2015

Exhibit 10.3

EXECUTION COPY

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT, dated as of November 18, 2014 (this "Agreement"), by and between MELA Sciences, Inc. (the "Company"), a Delaware corporation, and Michael R. Stewart ("Employee"), an individual.

WITNESSETH:

WHEREAS, the Company desires to employ Employee, and Employee wishes to be employed by the Company, on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties hereto, the parties hereby agree as follows:

1. Term. The initial term of Employee's employment hereunder shall commence on December 15, 2014 (the "Effective Date") and end on the third anniversary thereof (the "Initial Term"), unless sooner terminated in accordance with Section 5 hereof. Upon expiration of the Initial Term, Employee's employment with the Company hereunder shall be extended for successive one-year periods unless either party provides written notice to the other party at least 45 days prior to the end of the then current term, of its election to terminate this Agreement at the end of such then current term. The period during which this Agreement is in effect is hereafter referred to as the "Term."

2. Duties and Services. Employee agrees to serve the Company as its President and Chief Executive Officer, reporting to the Board of Directors of the Company and any authorized committee thereof (the "Board"). Employee shall have overall responsibility for the business, strategy and operations of the Company. Employee agrees to devote his full and entire business time, attention, skill and efforts to perform services for the Company and to faithfully and diligently discharge and fulfill his duties hereunder to the best of his abilities and shall be engaged in other business activities only to the extent that such other activities do not materially interfere or conflict with his obligations to the Company hereunder. In no event shall Employee's other business activities violate his obligations under Section 7 below. The foregoing also shall not be construed as preventing Employee from (a) with the prior consent of the Board, serving on civic, educational, philanthropic or charitable boards or committees or on up to two corporate boards (but not as chairman of the board), and (b) managing personal investments, so long as such activities are permitted under the Company's Code of Conduct and employment policies. Exhibit A to this Agreement contains a list of the other business and professional activities in which Employee is currently engaged and have been approved to the extent set forth on Exhibit A. Employee shall perform his duties hereunder at the Company's principal offices, currently located in Irvington, New York, with travel to such other places and at such times as the needs of the Company may from time-to-time dictate or be desirable.

3. Compensation.

(a) During the Term, the Company agrees to pay or cause to be paid to Employee, and Employee agrees to accept, a salary for all of Employee's services at the rate of $310,000 per annum (the "Base Salary"), payable in accordance with the Company's payroll practices and policies in effect from time to time and subject to applicable withholding of income taxes, social security taxes and other such other payroll deductions as are required by law or applicable employee benefit programs.

(b) With respect to each fiscal year of the Company during the continued full-time employment of Employee hereunder, commencing with the 2015 fiscal year, Employee will be eligible to receive an annual cash bonus of up to 50% of Employee's Base Salary (a "Cash Bonus") based on the achievement of certain performance-based targets and other objectives as may be established by the Board based on annual Company budgets approved by the Board from time to time. The terms of Employee's Cash Bonus opportunity for each fiscal year shall be separately communicated to Employee by the Board, after consultation with Employee, prior to the commencement of such fiscal year. Any Cash Bonus allocable to Employee hereunder shall be earned by Employee if and only if Employee remains actively employed on a full-time basis with the Company and is otherwise in compliance with Employee's obligations under this Agreement through the end of the fiscal year to which such Cash Bonus relates. Any Cash Bonus awarded to Employee hereunder will be payable in a single lump sum cash payment, less applicable taxes and withholdings, not later than two and one-half months after the end of the fiscal year to which it relates in accordance with the Company's customary practices for annual bonus payments.

(c) In addition to Employee's Base Salary and any Cash Bonus that may be earned and payable hereunder, Employee shall be granted stock options subject to the Company's customary Stock Option Agreement under the Company's 2013 Stock Incentive Plan (the "Plan") to purchase up to 750,000 shares of the Company's common stock at fair market value on the date of grant, as provided in the Plan, subject to the following vesting schedule:

(i) stock options to purchase up to 375,000 shares of the Company's common stock to vest in three equal installments of 125,000 shares each on the first, second and third anniversaries of the date of this Agreement; provided, however, that vesting shall accelerate and the right to purchase all such shares shall vest in full at such time as there is a Change in Control (as defined in Section 5(d) hereof) of the Company; and

(ii) stock options to purchase up to 375,000 shares of the Company's common stock to vest in three annual installments of up to 125,000 shares each upon a determination by the Board that the Company has achieved the following milestones for the 2015, 2016 and 2017 fiscal years, respectively: (A) one-third if the Company achieves the revenue plan established by the Board for such year, (B) one-third if the Company achieves the EBITDA plan established by the Board for such year, and (C) one-third if the Company achieves the goals established by the Board for such year as set forth in writing within 30 days after the date of this Agreement; provided, however, that any such stock option that has not vested with respect to any particular year due to the failure to satisfy a milestone condition for that year shall terminate as of the end of that year and shall no longer become exercisable; and provided further, however, all such stock options that have not previously terminated shall accelerate and vest in full at such time as there is a Change in Control (as defined in Section 5(d) hereof) of the Company.

All such stock options shall be incentive stock options to the extent permitted by applicable law.

4. Employee Benefits; Vacation; Expenses. During the Term:

(a) Employee shall be entitled to participate, in accordance with the terms and conditions thereof, in any standard group benefit plans maintained generally for senior level employees of the Company, as the same may be in effect or amended from time to time. The foregoing, however, shall not be construed to require the Company to establish any such plans, or to prevent the Company from modifying or terminating any such plans once established. In addition to standard group benefit plans, during the Term the Company shall reimburse Employee for his reasonable out-of-pocket costs of supplemental term life insurance in the coverage amount of $1 million and a supplemental disability policy with coverage limits common to Employee's salary level.

(b) Employee shall be entitled to vacation commencing with the 2015 fiscal year at the rate of four weeks per year, taken consecutively or in segments, subject to the effective discharge of Employee's duties and responsibilities hereunder. Vacation time will accrue on a monthly basis during any such year, and any accrued vacation time not taken during the year in which it accrued shall not have a cash value and may be rolled over to the following or any subsequent year only to the extent permitted and in accordance with then current Company policy.

(c) The Company shall reimburse Employee for the reasonable and necessary out-of-pocket business expenses incurred by Employee for or on behalf of the Company in furtherance of the performance of Employee's duties hereunder in accordance with the Company's policies as approved by the Board from time to time, subject in all cases to the Company's requirements with respect to reporting and documentation of such expenses.

(d) During the first year of the Initial Term, the Company shall pay or reimburse Employee for reasonable costs of temporary housing in the Irvington, New York area, currently estimated at $3,000 per month. After the first year of the Initial Term, the Company shall pay Employee an automobile allowance of $1,000 per month.

5. Termination.

(a) Notwithstanding anything to the contrary contained herein, Employee's employment under this Agreement, as well as Employee's right to any Base Salary, Cash Bonus and/or other benefits that thereafter otherwise would accrue to Employee hereunder, shall terminate upon the earliest to occur of the following events:

(i) The death of Employee;

(ii) The disability (as hereinafter defined) of Employee;

(iii) In the event of Employee's voluntary decision to terminate his employment with the Company, upon the date set forth therefor in a written notice of such termination received by the Company from or on behalf of Employee; provided that the termination date shall not be sooner than two weeks following the Company's receipt of such notice;

(iv) Upon written notice of such termination to Employee from or on behalf of the Company or the Board (or at such later date specified therein) if: (A) there shall be "Cause" (as hereinafter defined) or (B) Employee shall have advised the Company or the Board of Employee's intention to terminate his employment with the Company;

(v) Upon a Change of Control (as defined in Section 5(d)) of the Company unless the new controlling person or entity of the Company's business and/or assets determines otherwise; or

(vi) Upon written notice of such termination to Employee from or on behalf of the Company or the Board, other than under a circumstance covered by, or when facts exist that would comprise, any of clauses (i), (ii), (iii), (iv) or (v) of this Section 5(a).

(b) Employee shall be deemed to be under a "disability" for purposes hereof, at the option of the Company by written notice to Employee, (i) if Employee and the Board agree that Employee is disabled, or (ii) in the event that Employee shall be unable to or shall fail to render and perform the services required of Employee under this Agreement for 30 consecutive days or an aggregate of 60 days in any consecutive 12-month period because of physical or mental incapacity or disability, such option to be exercisable by the Company.

(c) For purposes of this Agreement, the term "Cause" is defined as: (i) the conviction of Employee for a felony or a crime involving moral turpitude; (ii) Employee's material violation of any written Company policy or the material terms of this Agreement after written notice of such failure and failure to cure within 20 business days; (iii) Employee's failure to follow a lawful direction of the Board after written notice of such failure and failure to cure within 20 business days; (iv) a breach by Employee of a fiduciary responsibility owing to the Company or any of its affiliates; (v) Employee's failure to perform such duties as are reasonably delegated or assigned to Employee after written notice of such failure and failure to cure within 20 business days; (vi) drug or alcohol abuse by Employee, but only if the Employee fails to seek appropriate counseling or fails to complete a prescribed counseling program to the reasonable satisfaction of the Board; and (vii) a breach by Employee of Section 7 of this Agreement or any other obligation relating to non-competition, non-solicitation of employees, customers, licensees or licensors, confidentiality, or ownership and/or rights as to creations and/or proprietary information or property, under any written agreement in effect from time to time, in favor of the Company.

(d) For purposes of this Agreement, the term "Change of Control" is defined as: (i) any "person," as such term is used in sections 13(d) and 14(d) of Securities Exchange Act of 1934, as amended, (the "Exchange Act") becomes the beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; provided, however, that no Change of Control shall be deemed to occur by reason of the acquisition of securities of the Company by one or more investors in the Company in capital-raising transactions; (ii) the direct or indirect sale or exchange by the stockholders of the Company of all or substantially all of the outstanding capital stock of the Company; (iii) a merger or consolidation in which the Company is a party and in which the stockholders of the Company before such Change of Control do not retain, directly or indirectly, at a least majority of the beneficial interest in the voting stock of the Company after such transaction; or (iv) an agreement for the sale or disposition by the Company of all or substantially all the Company's assets.

(e) Severance; Release.

(i) In the event of, and only upon, the termination of the employment of Employee under this Agreement pursuant to: (A) Section 5(a)(v) and either (x) Employee has not been offered post-Change of Control employment by the Company or any successor entity; or (y) if offered post-Change of Control employment by the Company or any successor entity, the position offered to Employee would result in a material reduction in Employee's duties, authority or responsibilities as in effect immediately prior to such Change of Control; or (B) Section 5(a)(vi), then Employee shall be entitled to receive (I) his Base Salary and the amount of any Cash Bonus earned hereunder but unpaid through the date of such termination, any benefits referred to in the first sentence of Section 4(a) in which Employee has a vested right under the terms and conditions of the employee benefit plan pursuant to which such benefits were granted ("Vested Benefits"), and (II) (a) severance in an amount equal to Employee's then current Base Salary for 12 months payable in equal installments, less applicable taxes and withholdings, pursuant to the Company's normal payroll procedures over 12 months as provided herein, and (b) provided Employee timely elects, and remains eligible for, continued group health plan benefits to the extent authorized by and consistent with 29 U.S.C. § 1161 et seq. (commonly known as "COBRA"), reimburse Employee, on a monthly basis upon presentation of proof of payment by Employee, for COBRA premiums in an amount such that Employee's net cost (after tax) for continued health insurance coverage is the same as Employee's cost for such benefits as in effect on the date of termination and such reimbursement shall continue until the earlier of: (i) the date that is 12 months after the date of termination, and (ii) the date Employee becomes eligible for health benefits through another employer or otherwise become ineligible for COBRA (the "Termination Benefits"). Any severance payments due hereunder shall commence as soon as administratively feasible within 60 days after Employee's termination of employment provided Employee has timely executed and returned the Release referred to in Section 5(e)(iii) and, if a revocation period is applicable, Employee has not revoked the Release; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the severance payments shall begin to be paid in the second calendar year. On the date that severance payments commence, the Company will pay Employee in a single lump sum payment, less applicable taxes and withholding, the severance payments that Employee would have received on or prior to such date but for the delay imposed by the immediately preceding sentence, with the balance of the severance payments to be paid as originally scheduled. Solely for purposes of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), each installment payment is considered a separate payment. To the full extent permitted by Code section 409A, it is intended that any severance amount shall be exempt from the requirements of Code section 409A by reason of either (1) the exemption set forth in Treas. Regs. 1.409A-1(b)(9)(iii) or (2) the short-term deferral rule under Treas. Regs. 1.409A-1(b)(4).

(ii) In the event that Employee's employment terminates under any circumstance other than as described in clause (i) of Section 5(e), then the Company shall not be obligated to make any Termination Benefits to Employee or to provide any other severance, termination or similar payments or compensation or benefits, regardless of any general or other policy, plan or practice as to severance or employment termination in effect from time to time, other than Base Salary and any Cash Bonus earned but unpaid through the date of such termination and any Vested Benefits.

(iii) Notwithstanding anything to the contrary set forth herein, the obligation to pay any Termination Benefits is expressly conditioned upon the execution by Employee and delivery to the Company of, and the effectiveness (after the expiration of any and all revocation and cancellation periods and rights) of, such separation agreement and general release from Employee, in such form as shall be required by the Company (the "Release") and Employee has returned all Company property and resigned from all positions with the Company and any affiliated company. In no event shall any Termination Benefits be payable unless and until such separation agreement and general release becomes effective and all statutory rights to rescind, revoke or terminate the same have expired unexercised.

(iv) Any Termination Benefits earned hereunder shall be in lieu of any other claim for compensation whether under this Agreement, or under any wage continuation law or at common law or otherwise, or any and all claims to severance or similar payments or benefits which Employee may otherwise have or make, except that Employee may still seek unemployment insurance without any adverse consequence hereunder. Without limiting any other rights or remedies which the Company may have, the Company shall be under no obligation to pay any Termination Benefits, and Employee shall immediately reimburse the Company in full for any and all Termination Benefits paid to Employee hereunder if Employee violates any of the provisions of Section 7.

(f) Parachute Provisions. Payments under this Agreement shall be made without regard to whether the deductibility of such payments (or any other payments) would be limited or precluded by Section 280G of the Code, and without regard to whether such payments would subject Employee to the federal excise tax levied on certain "excess parachute payments" under Section 4999 of the Code; provided, however, that if the Total After-Tax Payments (as defined below) would be increased by the limitation or elimination of any amount payable under this Agreement, then the amount payable under this Agreement will be reduced to the extent necessary to maximize the Total After-Tax Payments. The determination of whether and to what extent payments under this Agreement are required to be reduced in accordance with the preceding sentence will be made by the Company's independent auditors. In the event of any underpayment or overpayment under this Agreement (as determined after the application of this Section 5(f)), the amount of such underpayment or overpayment will be immediately paid by the Company to Employee or refunded by Employee to the Company, as the case may be, with interest at the applicable federal rate provided for in Section 7872(f)(2) of the Code. For purposes of this Agreement, "Total After-Tax Payments" means the total of all "parachute payments" (as that term is defined in Section 280G(b)(2) of the Code) made to or for the benefit of Employee (whether made hereunder or otherwise), after reduction for all applicable federal taxes (including, without limitation, the tax described in Section 4999 of the Code).

6. Deductions and Withholding. Employee agrees that the Company shall be entitled to withhold from any and all payments required to be made to Employee pursuant to this Agreement all federal, state, local and/or other taxes which it determines are required to be withheld in accordance with applicable statutes and/or regulations from time to time in effect.

7. Restrictive Covenants.

(a) For and in consideration of the rights of Employee under Sections 3, 4 and 5(e), the adequacy and sufficiency of which are hereby irrevocably acknowledged by Employee, Employee agrees that Employee shall not, and shall not permit any person or entity directly or indirectly controlled by Employee (alone or together with others) (the "Employee Affiliates") to, directly or indirectly (including, without limitation, through ownership, management, operation or control of any other person or entity, or participation in the ownership, management, operation or control of any other person or entity, or by having any interest, as a stockholder, lender, investor, agent, consultant, employee, partner or otherwise, in or with respect to any other person or entity) do any of the following:

(i) during the period of Employee's employment with the Company and for 12 months following the date of termination of Employee's employment for any reason (the "Restricted Period"), own, manage, operate, control, invest in, participate in, provide consulting services to, or be involved or associated with in any capacity, any person or entity that competes directly or indirectly with the business conducted by the Company or proposed to be conducted by the Company during the time Employee was employed by the Company or during the Restricted Period, within the geographical areas in which the Company is doing business or proposes to do business at the time of Employee's termination of employment; provided that the foregoing shall not prohibit Employee and Employee Affiliates from owning in the aggregate less than one percent of any class of securities listed on a national securities exchange or traded publicly in the over-the-counter market; Employee acknowledges that the Company conducts business on a nationwide and international basis, that its sales and marketing prospects are for expansion into national and international markets not currently penetrated and that, therefore, the territorial and time limitations set forth in this Section are reasonable and properly required for the adequate protection of the business of the Company.

(ii) during the Restricted Period, (A) solicit, encourage or entice any client, customer, vendor, licensee, licensor, consultant or supplier of or to the Company to cease to do business with, or to reduce or modify the business such person or entity has done with or intends to do with, or to end, reduce or modify any relationship or proposed relationship of such person or entity with, the Company, or (B) interfere with, disrupt or attempt to disrupt or otherwise jeopardize any relationship of the Company with any client, customer, vendor, licensee, licensor, consultant or supplier or any other person or entity with whom the Company has a business relationship;

(iii) during the Restricted Period, encourage, entice or induce any person who at the time of Employee's termination of employment or at any time during the 18-month period immediately preceding such termination is or was an employee of, or a consultant to, the Company to leave the employ of, or to terminate any such consulting arrangement with, the Company, or, with respect to any such employee or consultant who is then an employee of or consultant to the Company, to become an employee of, or consultant to, any other person or entity, or employ or retain any such person; or

(iv) during the Restricted Period and at all times thereafter, disparage, criticize or make statements which may be perceived as negative, detrimental or injurious to the Company, or any of the management, owners, business, policies or practices of the Company; provided that the Restricted Period and any additional periods thereafter under this Section 7 shall be tolled and shall cease to run during the period of any violation by Employee of any of Employee's agreements and obligations under this Section 7.

(b) Employee acknowledges and agrees that Employee's employment by the Company will necessarily involve Employee's understanding of and access to trade secrets and confidential or proprietary information and property, and personal information pertaining to the business and affairs of the Company, and its licensors, clients, customers, licensees, consultants and suppliers of or to any of them, including, without limitation, data, databases, know-how, trade secrets, marketing plans and opportunities, cost and pricing information, strategies, forecasts, licensee and customer lists, reports and surveys, concepts and ideas, computer software, systems and programs (including source code and documentation), and techniques and technical information, whether acquired by, or provided or made available to, Employee before, on or after the date of this Agreement by reason of Employee being or having been an employee of the Company and Employee agrees to keep all such information confidential. Employee and the Company have entered into that certain Employee Confidentiality and Invention Agreement dated as of the date hereof (the "Confidentiality Agreement") and attached hereto as Exhibit B, the terms and conditions of which are incorporated by reference herein and made a part hereof. The terms and provisions of this Agreement shall control and govern in respect of any conflict between the terms of this Agreement and the Confidentiality Agreement.

(c) Employee represents that his employment with the Company will not violate or conflict with any obligations to any previous employer or other party, including without limitation, obligations relating to nondisclosure, proprietary information, non-competition and non-solicitation.

(d) Because irreparable harm would be sustained by the Company in the event that there is a breach by Employee of any of the terms, covenants and agreements set forth in this Section 7, in addition to any other rights and remedies that the Company may otherwise have, the Company shall be entitled to obtain specific performance and/or injunctive relief against Employee from any court of competent jurisdiction, without making a showing that monetary damages would be inadequate and without the requirement of posting any bond or other security whatsoever, in order to enforce or prevent any breach or threatened breach of any of the terms, covenants and agreements set forth in this Section 7.

(e) Each of the obligations of Employee under this Section 7 shall survive the termination of Employee's employment by the Company for any reason whatsoever.

(f) Employee acknowledges that: (i) the enforcement of any of the restrictions on Employee or any other provisions contained in this Section 7 (the "Restrictive Covenants") against Employee would not impose any undue burden upon Employee; and (ii) none of the Restrictive Covenants are unreasonable as to duration or scope. If notwithstanding the foregoing, any provision of this Agreement would be held to be invalid, prohibited or unenforceable in any jurisdiction for any reason (including, without limitation, any provision which may be held unenforceable because of the scope, duration or area of its applicability), unless narrowed by construction, such provision shall, as to such jurisdiction, be construed as if such invalid, prohibited or unenforceable provision had been more narrowly drawn so as not to be invalid, prohibited or unenforceable (and the court making any such determination as to any provision shall have the power to, and shall, modify such scope, duration or area or all of them, and such provision shall then be applicable in such modified form in such jurisdiction only). If, notwithstanding the foregoing, any provision of this Agreement would be held to be invalid, prohibited or unenforceable in any jurisdiction for any reason, such provision, as to such jurisdiction, shall be ineffective to the extent of such invalidity, prohibition or unenforceability, without invalidating the remaining provisions of this Agreement, or affecting the validity or enforceability of such provision in any other jurisdiction.

(g) In the event that Employee's employment with the Company is terminated for any reason and Employee thereafter obtains employment or engagement by another person or entity (a "Subsequent Employer"), Employee agrees to advise such Subsequent Employer of Employee's continuing obligations under this Agreement.

8. No Conflicts. Employee represents and warrants that Employee is not party to any agreement, contract or understanding, whether of employment, consultancy or otherwise, in conflict with this Agreement or which would in any way restrict or prohibit Employee from undertaking or performing services for the Company. Employee hereby acknowledges that Employee has not foregone any other opportunity, financial or otherwise, in connection with Employee's execution and delivery of this Agreement or Employee's rendering of services to the Company.

9. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given and effective: (i) on the date of delivery, if delivered personally; (ii) on the first business day following the date of dispatch if delivered by a recognized next-day courier service; (iii) on the earlier of the fourth (4th) day after mailing or the date of the return receipt acknowledgment, if mailed, by certified or registered mail, return receipt requested, postage and fees prepaid; or (iv) on the date of transmission (subject to written confirmation of receipt), if sent by facsimile or e-mail .pdf to the other party hereto. Any such notice, if to Employee, shall be sent to Employee's address set forth on the signature page hereto or Employee's principal residence address then known to the Company, and, if to the Company, shall be sent to the Chairman of the Board. A copy of all notices sent by Employee to the Company pursuant to this Agreement shall also be sent to Duane Morris LLP, 30 South 17th Street, Philadelphia, PA 19103, Attn: Kathleen M. Shay. Either party may change the address to which notices, requests, demands and other communications hereunder shall be sent by sending written notice of such change of address to the other party in the manner hereinabove provided.

10. Assignability and Binding Effect. This Agreement shall inure to the benefit of and shall be binding upon the heirs, executors, administrators, successors and legal representatives of Employee, and shall inure to the benefit of and be binding upon the Company and its successors and assigns, but the obligations of Employee may not be delegated or assigned. Employee shall not be entitled to assign, transfer, pledge, encumber, hypothecate or otherwise dispose of this Agreement, or any of his rights hereunder, and any such attempted delegation or disposition shall be null and void and without effect. It is hereby acknowledged and agreed that the Company shall have the right to assign all or any part of its rights in respect of the covenants and agreements set forth in Section 7 of this Agreement to one or more direct or indirect acquirors of any of the assets or business of, or control of, the Company, and that this Agreement and all of the Company's rights and obligations hereunder may be assigned or transferred by the Company to and in such event may be assumed by any assignee of or successor to the Company.

11. Waiver and Compliance; Consents. Except as otherwise provided in this Agreement, any failure of either party to this Agreement to comply with any obligation, covenant, agreement or condition herein may be waived by the other party hereto only by written instrument signed by the party granting such waiver, but such waiver or failure to insist upon strict compliance with such obligation, covenant, agreement or condition shall not operate as a waiver of, or estoppel with respect to, any subsequent or other failure. Whenever this Agreement requires or permits consent by or on behalf of a party, such consent shall be given in writing in a manner consistent with the requirements for a waiver of compliance as set forth in this Section 11.

12. Entire Agreement; Amendments. This Agreement and the Confidentiality Agreement referenced herein sets forth the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and is expressly intended to supersede any and all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof. With respect to the subject matter hereof, no representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth. This Agreement shall not be altered, modified, amended or terminated except by written instrument signed by each of the parties hereto.

13. Headings, Construction, Interpretation. The captions and section headings contained in this Agreement are for convenience of reference only, do not form a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be deemed followed by the words "without limitation." When used in this Agreement, words such as "herein", "hereinafter", "hereof", "hereto", and "hereunder" shall refer to this Agreement as a whole, unless the context clearly requires otherwise. The use of the words "either" and "any" shall not be exclusive.

14. Code Section 409A. This Agreement shall be interpreted and administered to the extent practicable in a manner consistent with the following statement of intent: All benefits and compensation payable to Employee pursuant to this Agreement are intended to be exempt from the definition of "nonqualified deferred compensation plan" or "deferral of compensation" under Code Section 409A in accordance with one or more exemptions available under the Treasury Regulations promulgated under Code Section 409A. To the extent that any benefit or payment is or becomes subject to Code Section 409A, this Agreement is intended to comply with the requirements of Code Section 409A as applicable to such benefit or payment.

15. Governing Law; Venue. This Agreement and the legal relations among the parties shall be governed by the internal laws of the State of New York, without regard to principles of conflict of laws. Any litigation arising in connection with or related to this Agreement or any of the subject hereof shall be tried solely by and in the United States District Court for the Southern District of New York, provided that, if such litigation shall not be permitted to be tried by such court, then such litigation shall be held solely in the state courts of New York sitting in New York City. Each party hereto irrevocably consents to and confers personal jurisdiction on the United States District Court for the Southern District of New York, or, if (but only if) the litigation in question shall not be permitted to be tried by such court, on the state courts of New York sitting in New York City, and expressly waives any objection to the venue of such court, as the case may be and any argument that any case filed should be transferred to a more convenient forum.

16. Mutual Waiver of Jury Trial. EACH PARTY HERETO HEREBY WAIVES THE RIGHT TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING BASED UPON, ARISING OUT OF, OR IN ANY WAY RELATING TO THIS AGREEMENT, OR THE EMPLOYMENT OF EMPLOYEE, WHETHER SOUNDING IN CONTRACT OR TORT OR OTHERWISE. EACH PARTY HERETO AGREES THAT EITHER OF THEM MAY FILE A COPY OF THIS AGREEMENT UNDER SEAL WITH THEY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED AGREEMENT BETWEEN THE PARTIES IRREVOCABLY TO WAIVE TRIAL BY JURY, AND THAT ANY DISPUTE OR CONTROVERSY WHATSOEVER BETWEEN THEM SHALL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

17. Knowing and Voluntary Agreement. The parties to this Agreement acknowledge and agree that each of them has had a full and fair opportunity to carefully read and review the terms and provisions of this Agreement and consult with their own attorney concerning the meaning and effect of this Agreement. By executing this Agreement, each of the parties hereto represents, acknowledges, and agrees that such party fully understands his or its right to discuss all aspects of this Agreement with his or its own attorney, that to the extent he or it wanted to talk to his or its attorney he or it has availed herself or itself of that right, that he or it has carefully read and fully understands all the provisions of this Agreement, and that he or it is knowingly and voluntarily entering into this Agreement and signing it of his or its own free will.

18. Interpretation. In the event any ambiguity or question of intent or interpretation arises, this Agreement shall be construed as drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring either party by virtue of the authorship of any of the provisions of this Agreement. No provision of this Agreement shall be construed against either party on the grounds that such party or its counsel drafted that provision.

19. Counterparts; Signatures. This Agreement may be executed in any number of counterparts with the same effect as if all parties hereto had signed the same document. All counterparts shall be construed together and shall constitute one Agreement. This Agreement and any amendments hereto, to the extent signed and delivered by means of a facsimile machine or electronic transmission, shall be treated in all manner and respects as an original Agreement and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of either party hereto the other party hereto shall re-execute original forms thereof and deliver them to such requesting party. No party hereto shall raise the use of a facsimile machine or electronic transmission to deliver a signature or the fact that any signature was transmitted or communicated through the use of facsimile machine or electronic transmission as a defense to the formation of a contract and each such party forever waives any such defense.

[*Balance of page intentionally left blank; signature page follows.*]

IN WITNESS WHEREOF, the parties hereto have executed this Employment Agreement as of the day and year first above written.

COMPANY:

MELA SCIENCES, INC.

By: /s/ Jeffrey F. O'Donnell
Jeffrey F. O'Donnell,
Chairman of the Board

EMPLOYEE:

/s/ Michael R. Stewart
Michael R. Stewart

EXHIBIT A

Other Activities

Board of Directors of Polymerx

EXHIBIT B

Confidentiality Agreement

This EMPLOYEE CONFIDENTIALITY AND INVENTION AGREEMENT is made, as of _____, 2014, by and between MELA Sciences, Inc. (the "Company"), a Delaware corporation, and Michael R. Stewart (the "Employee").

As a result of his employment by the Company, the Employee has had or will have access to and has or will become acquainted with various trade secrets and other proprietary and confidential information and property of the Company, the disclosure or use of which for any purposes other than in the Company's business would unreasonably and unfairly impair the Company's ability to conduct its business profitably.

THEREFORE, as a condition of and in consideration of the Company's employment or continuation of employment of the Employee, the Employee agrees with the Company as follows, intending to be legally bound hereby:

1. Certain Definitions. For purposes of this Agreement, the terms defined below have the meanings indicated.

1.1 "Affiliate." "Affiliate" means and includes any of the Company's subsidiaries (whenever formed or acquired), and any corporation, limited liability company, partnership, joint venture, association or other entity in which the Company owns or comes to own more than twenty percent of the voting stock or other ownership interest or which owns or comes to own twenty percent or more of the Company's outstanding common stock, and any of the Company's clients, customers, licensees, licensors, franchisees and franchisors.

1.2 "Confidential Matter." "Confidential Matter" means and includes the following:

All proprietary and confidential information of the Company consisting of techniques; formulas; designs; processes; programs; marketing data; equipment; documents; files; electronically recordable data or concepts; computer software and hardware; inventions; improvements; books; papers; compilations of information; records; specifications; names, addresses, names of agents and employees, buying habits and practices of existing and potential clients, customers and other Affiliates; various financial and operating data; names, marketing methods, practices and related information regarding the Company's existing and potential joint venture partners, licensees, licensors, vendors, suppliers and distributors; costs of materials; prices the Company obtains or has obtained or at which it sells, has sold or intends to sell its products or services; lists or other written records used in the Company's business; information regarding the Company's financial condition; compensation paid to the Company's consultants and employees and other terms of employment; and any of the foregoing that may have been or may be conceived, originated, discovered or developed by the Company or the Employee or any other employees or consultants of the Company while employed or engaged by the Company or on the basis of or using any Confidential Matter. All of the foregoing are owned and held in strict confidence by the Company or by Affiliates to which the Company has a duty of confidentiality. Nevertheless, "Confidential Matter" excludes any of the foregoing that has entered the public domain through no fault of the Employee, that an authorized executive officer of the Company has authorized for public dissemination, that was known to or possessed by the Employee prior to his employment by the Company and other than through disclosure or delivery by the Company, or that was learned or obtained by the Employee from sources having no duty of confidentiality to the Company that were or are unconnected with and unrelated to his employment by the Company.

2. Nondisclosure; Property.

2.1 Nondisclosure. The Employee acknowledges and agrees that, as an employee of the Company, he has had and/or will have access to and has and/or will become acquainted with Confidential Matter, all of which the Employee will regard and protect as trade secrets owned by the Company and all of which are used or contemplated to be used in the Company's business. The Employee represents, warrants and agrees that, except as required by the Company in the course of his employment with the Company, he will not at any time, whether during or after his employment by the Company, directly or indirectly, use or permit others to use, or disclose or communicate to any person or entity, any Confidential Matter, without the prior written consent of an executive officer of the Company in the particular case.

2.2 Property. The Employee agrees that he will not make or retain any originals, copies or reproductions of or excerpts from any of the Confidential Matter for his use or the use of others and, on request by the Company or on termination of the Employee's employment with the Company, the Employee will deliver to the Company all tangible property that is or embodies any of the Confidential Matter, whether prepared or developed by or with the assistance of the Employee or otherwise coming into his possession, control or knowledge.

2.3 Nondisclosure to the Company. The Employee further represents and warrants that the Employee has not disclosed and will not disclose to the Company or any Affiliate any trade secrets or other proprietary or confidential information that may not lawfully be so disclosed by the Employee, by virtue of the ownership of the same by another person or entity or otherwise.

3. Inventions, Designs and Patents.

3.1 Disclosure and Assignment of Inventions. The Employee agrees that he will promptly and fully disclose to the Company, and the Company agrees to keep confidential, all inventions, designs, creations, processes, technical or other developments, improvements, ideas and discoveries (collectively, "Inventions"), whether patentable or not, of which the Employee obtains knowledge or information during his employment with the Company and for a period of one year thereafter and which relate to the existing or contemplated products, services or business of or to any research or experimental, developmental or creative work carried on or contemplated by the Company, whether or not conceived, originated, made, developed or reduced to practice by the Employee alone or with others during regular working hours or at other times. All Inventions are and shall remain the exclusive property of the Company. The Employee agrees that he will assign, and hereby does assign, to the Company or its designee, all of the Employee's right, title and interest in and to all Inventions, whether patentable or not, conceived, originated, made, developed or reduced to practice by the Employee, alone or with others, while he is an employee with the Company.

3.2 Cooperation. The Employee agrees to assist the Company to obtain any and all patents, copyrights, trademarks and service marks relating to Inventions and to execute all documents and do all things necessary to obtain letters patent and copyright, trademark and service mark registrations therefor, to vest the Company or its designee with full and exclusive title thereto and to protect the same against infringement by others, all as and to the extent the Company may request and at the Company's expense, for no consideration to the Employee other than the Employee's salary or wages.

3.3 Exceptions. Sections 3.1 and 3.2 shall not, however, apply to an Invention developed entirely on the Employee's own time without using the Company's or any Affiliate's equipment, supplies, facilities or trade secret information except for those Inventions that either (a) relate at the time of conception or reduction to practice of the Invention to the Company's business or demonstrably anticipated research or development of the Company, or (b) result from any work performed by the Employee for the Company. The Employee has provided to the Company a complete and accurate written list, which the Company agrees to keep confidential, of all unpatented Inventions owned, conceived, originated, made, developed or reduced to practice by the Employee (whether or not prior to the Employee's employment with the Company) qualifying for the exception in the first sentence of this section 3.3.

4. Trade Secrets of Third Parties. The Employee acknowledges and understands that, in dealing with existing and potential Affiliates, suppliers, contracting parties and other third parties with which the Company has business relations or potential business relations, the Company frequently receives confidential and proprietary information and materials from such third parties subject to the Company's understanding that the Company will maintain the confidentiality thereof and will require its employees and consultants to do so. The Employee agrees to treat all such information and materials as Confidential Matter subject to this Agreement.

5. Injunctive Relief. The Employee acknowledges and agrees that his failure to perform any of his covenants in this Agreement would cause irreparable injury to the Company and cause damages to the Company that would be difficult or impossible to ascertain or quantify. Accordingly, without limiting any remedies that may be available with respect to any breach of this Agreement, the Employee consents to the entry of an injunction to restrain any breach of this Agreement.

6. Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision hereof.

7. Attorneys' Fees. If suit is brought to enforce or interpret this Agreement, the prevailing party shall be entitled to recover as an element of costs of suit, and not as damages, reasonable attorneys' fees and expenses and all expert witnesses' fees and expenses incurred by the prevailing party. In such event, the "prevailing party" shall be the party that is entitled to recover costs of suit, whether or not the suit proceeds to final judgment, the party not entitled to recover costs shall not recover attorneys' or expert witnesses' fees or expenses and no sum for attorneys' and expert witnesses' fees and expenses shall be counted in calculating the amount of a judgment for purposes of determining whether a party is entitled to recover costs or attorneys' or expert witnesses' fees or expenses.

8. **Headings.** The section headings in this Agreement are for convenience of reference only and are not part of this Agreement.

9. **Notices.** Any notice, consent or other communication to be given under or in connection with this Agreement shall be in writing and shall be deemed duly given and received when delivered personally, when transmitted by facsimile if receipt is acknowledged by the addressee, one day after being deposited for next-day delivery with a nationally recognized overnight delivery service or three days after being mailed by first class mail, charges or postage prepaid, properly addressed, if to the Company, at 50 South Buckhout Street, Irvington, New York 10533 (Facsimile number: (914) 591-3785), and, if to the Employee, at his address or facsimile number appearing on the records of the Company. Either the Company or the Employee may change its or his address for this purpose from time to time by notice to the other.

10. **Successors.** This Agreement shall inure to the benefit of and bind the Company and the Employee and their respective successors, assigns, heirs, legatees, devisees and personal representatives.

11. **Entire Agreement.** This Agreement contains the entire agreement of the Company and the Employee and supersedes all prior or contemporaneous negotiations, correspondence, understandings and agreements, whether written or oral, between them, with respect to the subject matter hereof.

12. **Survival.** All agreements, representations, warranties and acknowledgments herein shall survive any termination of the Employee's employment with the Company for any reason.

13. **The Company's Right to Terminate.** Nothing herein shall be interpreted to impair or otherwise affect the right and power of the Company to terminate its employment of the Employee, which is at will.

14. **Acknowledgement.** THE EMPLOYEE HEREBY WARRANTS AND ACKNOWLEDGES THAT HE HAS CAREFULLY READ AND UNDERSTANDS ALL OF THE PROVISIONS OF THIS AGREEMENT.

(Signature page follows.)

IN WITNESS WHEREOF, the parties have entered into this Agreement as of the date first above written.

EMPLOYEE:

_____

Michael R. Stewart

MELA SCIENCES, INC.

By: _____

Name: _____

Title: _____

Exhibit 10.4

EXECUTION COPY

CONFIDENTIAL GENERAL RELEASE AND SEVERANCE AGREEMENT

This Confidential General Release and Severance Agreement (this "AGREEMENT") is made and entered into by and between Rose Crane, on behalf of herself, her spouse or domestic partner, agents, representatives, attorneys, assigns, beneficiaries, heirs, executors, administrators, and anyone who has or obtains any legal rights or claims through her (hereinafter collectively referred to as "CRANE"), and MELA Sciences, Inc. ("MELA"). Each of MELA and CRANE may be referred to individually as a "PARTY" or collectively as the "PARTIES," as is contextually appropriate.

WHEREAS, CRANE was employed by MELA as President and Chief Executive Officer pursuant to a certain Employment Agreement dated as of November 6, 2013 ("Employment Agreement"); and

WHEREAS, CRANE's employment terminated as of the close of business on November 17, 2014 and prior to the expiration of the Initial Term of the Employment Agreement, as defined therein; and

WHEREAS, CRANE is not entitled to severance of any kind whatsoever under the Employment Agreement; and

WHEREAS, CRANE and MELA desire to settle, fully and finally, any and all differences that may exist between them arising out of or relating to CRANE's employment relationship with MELA and the termination of her employment with MELA, with each PARTY assuming their own costs and attorneys' fees, respectively.

Accordingly, in consideration of the mutual covenants and promises that CRANE and MELA have made to the other as set forth in this AGREEMENT, CRANE and MELA agree as follows:

1. Monetary Consideration.

In consideration for CRANE's promises made herein, MELA agrees to pay to Crane (a) the gross amount of One Hundred Fifty Thousand Dollars ($150,000.00) subject to all applicable withholdings and deductions as required by law (the "Payment"), and (b) any accrued but unused vacation time. The Payment shall be paid over a period of six (6) months in accordance with MELA's payroll practices commencing on the regular payroll date next following CRANE's execution of this AGREEMENT without revocation.

The Payment is made in full, final and complete settlement for any claims CRANE could make concerning her employment or termination of employment with MELA, in consideration for the AGREEMENT, and shall serve to compensate CRANE in full.

CRANE agrees that the Payment shall constitute the entire monetary consideration provided to her under this AGREEMENT and the Employment Agreement, and that she will not seek any further compensation for any other claimed damages, costs, or attorneys' fees in connection with the matters encompassed in this AGREEMENT.

2. Liability for Taxes. CRANE understands and agrees that neither MELA, nor any of its officers, directors, employees, affiliates, insurers or agents (collectively the "MELA Representatives"), nor any of MELA's attorneys are providing tax or legal advice, or making representations regarding tax obligations or consequences related to this AGREEMENT or the Payment. CRANE further agrees that she will assume any such tax obligations or consequences that may arise from the Payment, and that she is not entitled to nor shall she seek any indemnification from MELA or any of the MELA Representatives, or MELA's attorneys, in this regard. CRANE agrees to indemnify and hold MELA, all MELA Representatives and MELA's attorneys harmless from any claims, losses, demands, deficiencies, levies, assessments, executions, judgments, penalties, taxes, attorneys' fees and recoveries by any governmental entity against MELA, the MELA Representatives or MELA's attorneys for any failure by CRANE to pay taxes due and owing, if any, on the Payment.

3. Ownership of Claims. CRANE represents that she has not transferred or assigned, or purported to transfer or assign, to any person or entity, any claim described in this AGREEMENT. CRANE further agrees to indemnify and hold harmless MELA, the MELA Representatives and MELA's attorneys against any and all claims based upon, arising out of, or in any way connected with any such actual or purported transfer or assignment.

4. No Action Pending. CRANE represents that she has not filed any lawsuit, claim, charge, or complaint against MELA or any of the MELA Representatives with any local, state, or federal agency or court. In the event that any agency or court assumes jurisdiction of any lawsuit, claim, charge or complaint, or purports to bring any legal proceedings on CRANE's behalf against MELA or any of the MELA Representatives, then CRANE shall promptly request that the agency or court withdraw from and dismiss the lawsuit, claim, charge, or complaint with prejudice.

5. General Release. CRANE and MELA intend to effectuate with this AGREEMENT the complete extinguishment of any and all claims, known or unknown, and actions of any nature whatsoever, from the beginning of time to the effective date of this AGREEMENT, between CRANE and MELA, and to release and forever discharge MELA and all MELA Representatives of and from any and all manner of actions, causes of actions, charges, suits, rights to attorneys' fees or costs, debts, obligations, claims, and demands whatsoever in law or equity by reason of any matter, cause or thing whatsoever, and particularly, but without limitation of the foregoing general terms, by reason of any claims or actions arising from CRANE's previous employment or separation of employment with MELA. In addition, CRANE unconditionally releases, discharges, waives, and holds harmless MELA and all MELA Representatives from each and every other claim, cause of action, right, liability, penalty, expense, or demand of any kind and nature, whether or not presently known to exist.

With respect to the claims that CRANE is releasing and waiving, she is releasing and waiving not only her right to recover money or other relief in any action that she might institute, but also she is releasing and waiving her right to recover money or other relief in any action that might be brought on her behalf by any other person or entity including, but not limited to, representative class or collective action plaintiffs, the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, and each and any other federal, state or local governmental agency or department. Excluded from the release and waiver are any claims or rights that cannot be waived by law, such as CRANE's right to file a charge with an administrative agency or participate in any agency investigation. CRANE is, however, waiving her right to recover any money in connection with such a charge or investigation. If a lawful subpoena to testify before any entity is issued to CRANE, CRANE will immediately notify MELA and provide it with a copy of the subpoena.

This AGREEMENT is a full and final bar to any claims that CRANE may have against MELA and all MELA Representatives, including, without limitation, any claims:

(a) arising from CRANE's terms and conditions of employment, separation from employment, or the employment practices of MELA, including but not limited to claims alleging a violation of wages due, compensation and personnel policies, procedures, and handbooks, and discrimination claims;

(b) relating to any claims for punitive or compensatory damages; back and/or front pay claims and fringe benefits including disability benefits; wages; penalties; liquidated damages; interest; or payment of any attorneys' fees, costs or expenses for CRANE;

(c) arising under the federal Civil Rights Acts of 1866, 1871, 1964, and 1991, the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Family Medical Leave Act, the Fair Labor Standards Act, the Equal Pay Act, the Occupational Safety and Health Act, the Family and Medical Leave Act, the Consolidated Omnibus Reconciliation Act, the Genetic Information Nondiscrimination Act, the National Labor Relations Act, New York and federal Worker Adjustment and Retraining Notification Acts, the New York Human Rights Law, the New York City Administrative Code, and claims alleging discrimination or harassment or aider and abetter liability on the basis of age, race, color, gender (including sexual harassment), national origin, ancestry, disability, medical condition, religion, sexual orientation, marital status, parental status, veteran status, source of income, entitlement to benefits, union activities, or any other status protected by local, state or federal laws, constitutions, regulations, ordinances or executive orders; and

(d) based on any express or implied contract or covenant of good faith and fair dealing, tort, common law, negligence, constitutional, statutory, whistleblower, public policy, personal injury, invasion of privacy, defamation, libel, emotional distress, retaliation, detrimental reliance, or wrongful discharge theory, and all claims raised or that could have been raised.

CRANE expressly understands that among the various rights and claims being released and waived in this AGREEMENT are those arising under the **Age Discrimination in Employment Act**. This general release does not cover rights or claims under the Age Discrimination in Employment Act arising after CRANE signs this AGREEMENT.

6. Release of Unknown Claims. For the purpose of implementing a full and complete Release, CRANE expressly acknowledges that this AGREEMENT resolves all legal claims CRANE may have against MELA and all MELA Representatives as of the effective date of this AGREEMENT, including but not limited to claims CRANE did not know or suspect to exist in CRANE's favor at the time of the effective date of this AGREEMENT. CRANE hereby assumes any and all risk of any mistake in connection with the true facts involved in the matters, disputes or controversies described in this AGREEMENT or with regard to any facts that are now unknown to CRANE.

7. Covenant Not To Sue. A "covenant not to sue" is a legal term that means CRANE promises not to file a lawsuit in court. It is different from the General Release of claims contained in Section 5 above. Besides waiving and releasing the claims covered by Section 5 above, CRANE further agrees never to sue MELA or any of the MELA Representatives in any forum for any reason, including but not limited to claims, laws or theories covered by the Release language in Section 5 above. Notwithstanding this Covenant, CRANE may bring a claim against MELA to enforce this AGREEMENT. If CRANE sues MELA in violation of this AGREEMENT, CRANE shall be liable to MELA for its reasonable attorneys' fees and other litigation costs incurred in defending against such a suit. Furthermore, if CRANE sues MELA in violation of this AGREEMENT, MELA can require CRANE to return all but $1,000 of the money paid to her pursuant to this AGREEMENT. CRANE acknowledges the above provisions concerning attorneys' fees and costs and return of money are directly related to CRANE's breach of the AGREEMENT and do not apply in the event of a non-breaching occurrence, such as CRANE's participation in any agency investigation under the conditions set forth in Section 5.

8. Other Acknowledgements and Agreements by CRANE. CRANE agrees:

(a) she has been paid for all hours worked, including all wages and bonuses, she has no accrued but unused vacation due to her, she has not suffered any on-the-job injury for which she has not already filed a workers' compensation claim, she has received any leave to which she was entitled during her employment, she has not been retaliated or discriminated against because she took a family or medical leave or any reason protected by law, and MELA has not interfered with her ability to request or take such leaves;

(b) she understands the terms of this AGREEMENT; and

(c) some portion of the Payment provided in this AGREEMENT represents money over and above that to which she otherwise would be entitled upon her termination, that portion of the Payment would not have been provided had she not signed this AGREEMENT, and that portion of the Payment is in exchange for the signing of this AGREEMENT.

FURTHER, CRANE covenants and agrees to adhere to the restrictive covenants contained in Section 7 of her Employment Agreement, including but not limited to Sections 7(a)(i) through 7(a)(iv). CRANE acknowledges and agrees that the Section 7 restrictions survive her Employment Agreement and shall remain in full force and effect notwithstanding her termination of employment or anything contained in this AGREEMENT, and that any breach by CRANE of said restrictions shall constitute a material breach of the Employment Agreement and this AGREEMENT.

9. Non-Admission. CRANE acknowledges and agrees that the execution of this AGREEMENT and the consideration hereunder are not and shall not be construed in any way as an admission of wrongdoing or liability on the part of MELA, any of the MELA Representatives, or any other person. Neither this AGREEMENT nor anything in this AGREEMENT shall be construed to be or shall be admissible in any proceeding as evidence of liability or wrongdoing by MELA or any MELA Representative.

10. Confidentiality Agreement. It is understood and agreed that CRANE will not talk about, discuss or communicate with anyone, orally or in writing, including, but not limited to, current or former employees of or consultants to MELA or any customers, vendors, and suppliers of MELA, concerning the terms or existence of this AGREEMENT. Notwithstanding the foregoing: (i) CRANE may discuss this AGREEMENT with her immediate family, provided such persons agree to keep the information they receive confidential, (ii) CRANE may review this AGREEMENT with her accountant in connection with the filing of tax returns, (iii) CRANE may review this AGREEMENT with her attorney(s), and (iv) CRANE may truthfully testify under oath pursuant to a subpoena (in which event CRANE will provide MELA with prompt notice of the subpoena).

CRANE and MELA understand and acknowledge the promises set forth in this Section 10 are of paramount importance. CRANE and MELA understand and agree the actual amount of damages MELA will suffer if CRANE violates this Section 10 is dependent upon many circumstances, and it is impractical and extremely difficult to affix the actual damages. The PARTIES have endeavored to estimate the actual damages likely to be suffered in the event of a failure of CRANE to comply with the provisions of this Section 10, and the PARTIES agree that Five Thousand Dollars ($5,000.00) per occurrence is a reasonable estimate of the actual damages and is a just and reasonable sum under the circumstances. The PARTIES agree if CRANE violates this Section 10, the U.S. District Court for the Southern District of New York or other court of competent jurisdiction shall award MELA Five Thousand Dollars ($5,000.00) per occurrence as liquidated damages and not as a penalty or forfeiture.

In the event that CRANE is required by law or court order to disclose, publicize, or to permit, authorize or instigate the disclosure of this AGREEMENT, in whole or in part, CRANE must notify MELA in writing at least fifteen (15) business days prior to the disclosure in order to provide MELA an opportunity to object to such disclosure. Such written notification to MELA shall be sent to: MELA's Chief Executive Officer at MELA's principal place of business. CRANE agrees to cooperate fully with MELA if MELA decides to object to such disclosure; provided, however, that CRANE shall not be required to disobey any subpoena or court order.

11. **Full Cooperation.** CRANE understands and agrees that despite her termination from MELA, she shall use her best efforts in good faith to respond by email, telephone or otherwise to reasonable inquiries from MELA regarding any matters for which she was professionally responsible while employed at MELA.

12. **No Representations.** CRANE acknowledges that, except as expressly set forth herein, no representations of any kind or character have been made to induce the execution of this AGREEMENT.

13. **Attorneys' Fees; Breach.** In the event of CRANE's breach of any terms of this AGREEMENT or any of her obligations under the Employment Agreement, MELA may pursue any and all remedies allowable under state and federal law and the Company's obligations to make the Payment shall cease. Depending on the interpretation of applicable law, these remedies might include monetary damages, equitable relief, and recoupment of any previously paid portion of the Payment as set forth in Section 1 of this AGREEMENT. In the event that MELA prevails in any action for damages, injunctive relief, or to enforce the provisions of this AGREEMENT, MELA shall be entitled to an award of its reasonable attorneys' fees and all costs, including appellate fees and costs, incurred in connection therewith as determined by the court in any such action. CRANE acknowledges the above provisions concerning attorneys' fees and costs and return of consideration are directly related to CRANE's breach of the terms of this AGREEMENT or the Employment Agreement and do not apply in the event of a non-breaching occurrence, such as CRANE's participation in any agency investigation under the conditions set forth in Section 5.

14. **No Waiver.** The failure of CRANE and MELA, or either of them, to insist upon strict adherence to any term of this AGREEMENT on any occasion shall not be considered a waiver thereof, or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this AGREEMENT.

15. **Resignation from Positions; Return of Company Property.** CRANE agrees that she shall submit to MELA concurrently with her execution and delivery of this AGREEMENT her resignation as President, Chief Executive Officer and a director of MELA. CRANE hereby affirms that CRANE has, on or before the last day of employment with MELA, returned to MELA all originals and copies of all files, memoranda, documents, records, credit cards, keys, electronically stored copies of the foregoing, and any other property of MELA and/or any of the MELA Representatives, in CRANE's possession or control, including but not limited to MELA's office equipment, such as automobiles, computers and related equipment, files and telephones.

16. **Nondisparagement.** CRANE agrees not disparage, criticize or make statements that may be perceived as negative, detrimental or injurious to MELA or any MELA Representative or any of MELA's investors, consultants, suppliers, business, customers, products policies or practices, whether verbal, in writing, or in any other form, including form of electronic mail or social media.

17. Severability. The invalidity, illegality, or unenforceability of any provision of this AGREEMENT will not affect any other provision of this AGREEMENT, which shall remain in full force and effect. Nor will the invalidity, illegality or unenforceability of a portion of any provision of this AGREEMENT affect the balance of such provision. In the event that any one or more of the provisions contained in this AGREEMENT, or any portion thereof, is held to be invalid, illegal, or unenforceable in any respect, this AGREEMENT shall be reformed, construed, and enforced as if such invalid, illegal, or unenforceable provision had never been contained herein.

18. Governing Law. This AGREEMENT shall be governed by and construed in accordance with the laws of the State of New York without giving effect to conflict of laws. Any suit, action, or proceeding relating to this AGREEMENT shall be brought in the U.S. District Court for the Southern District of New York or other court of competent jurisdiction. The PARTIES hereby accept the exclusive jurisdiction of this court for the purpose of any such suit, action, or proceeding.

19. Entire Agreement. This AGREEMENT represents and contains the entire agreement and understanding among CRANE and MELA with respect to the subject matter of this AGREEMENT, and supersedes any and all prior oral and written agreements and understandings, and no representation, warranty, condition, understanding or agreement of any kind with respect to the subject matter hereof shall be relied upon by CRANE and MELA unless incorporated herein. This AGREEMENT may not be amended or modified except by an express written agreement signed by CRANE and MELA. Notwithstanding the foregoing, the terms of Section 7 of the Employment Agreement shall remain in full force and effect.

20. Agreement is Voluntary. CRANE acknowledges receipt of a copy of this AGREEMENT and understands and agrees that she:

a. has had a reasonable time within which to consider this AGREEMENT before executing it;

b. has carefully read and fully understands all the provisions of this AGREEMENT;

c. knowingly and voluntarily agrees to all of the terms set forth in this AGREEMENT;

d. knowingly and voluntarily intends to be legally bound by the same;

e. was advised, and hereby is advised in writing, to consider the terms of this AGREEMENT and consult with an attorney prior to executing this AGREEMENT; and

f. has been advised that she has twenty-one (21) days to consider this AGREEMENT before signing it, although CRANE may sign this AGREEMENT at any time within the twenty-one (21)-day period, and that she has elected to sign this AGREEMENT as of this date set forth below. CRANE and MELA agree that any change of the terms of this AGREEMENT shall not restart the twenty-one (21)-day period. CRANE understands she may revoke and declare this AGREEMENT null and void by providing written notice to the Chairman of the Board of MELA of her intent to revoke this AGREEMENT on or before 5:00 P.M. on the seventh (7^{th}) day following the signing of the AGREEMENT. CRANE understands this AGREEMENT will not become effective until after this seven (7)-day period passes.

21. Miscellaneous.

a. The language of all parts in this AGREEMENT shall be construed as a whole, according to its fair meaning, and not strictly for or against CRANE or MELA.

b. The headings used herein are for reference only and shall not affect the construction of this AGREEMENT.

22. Counterparts. This AGREEMENT may be executed in any number of counterparts, and any executed counterpart may be delivered via facsimile or electronically, and each such counterpart shall be deemed to be an original instrument but all such counterparts shall constitute one and the same agreement.

23. Good Faith Compliance. CRANE and MELA agree to cooperate in good faith and to do all things reasonably necessary to effectuate this AGREEMENT.

PLEASE READ CAREFULLY. THIS AGREEMENT INCLUDES THE FULL RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS THAT MAY HAVE ARISEN AT ANY TIME PRIOR TO THE EXECUTION OF THIS AGREEMENT.

[Signature page follows]

IN WITNESS WHEREOF, and intending to be legally bound, the PARTIES have executed this AGREEMENT as of the date first set forth above.

Dated: November 17, 2014

/s/ Rose Crane
Rose Crane

MELA SCIENCES, INC.

Dated: November 17, 2014

By /s/ Jeffrey F. O'Donnell
Jeffrey F. O'Donnell
Chairman of the Board

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements of MELA Sciences, Inc. ("the Company") on Forms S-3 (File No. 333-139056, File No. 333-145740, File No. 333-159274, File No. 333-189118, File No. 333-194649 and File No. 333-198249) and on Forms S-8 (File No. 333-136183 and File No. 333-161286 and File No. 333-189119) of our report dated March 30, 2015 with respect to our audits of the balance sheets of MELA Sciences, Inc. as of December 31, 2014 and 2013, and the related statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2014 included in the December 31, 2014 annual report on Form 10-K of MELA Sciences, Inc.

Our report dated March 27, 2015 contains an explanatory paragraph that states that the Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ EisnerAmper LLP

New York, New York
March 27, 2015

Exhibit 31.1

CERTIFICATION

I, Michael R. Stewart, certify that:

1. I have reviewed this report on Form 10-K of MELA Sciences, Inc.;

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

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

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

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

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

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

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

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

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

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

/s/ Michael R. Stewart
Michael R. Stewart
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 30, 2015

Exhibit 31.2

CERTIFICATION

I, Robert W. Cook, certify that:

1. I have reviewed this report on Form 10-K of MELA Sciences, Inc.;

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

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

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

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

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

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

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

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

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

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

/s/ Robert W. Cook
Robert W. Cook
Chief Financial Officer
(Principal Financial Officer)

Date: March 30, 2015

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned officers of MELA Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's Annual Report on Form 10-K for the period ended December 31, 2014 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael R. Stewart
Michael R. Stewart
President and Chief Executive Officer
(Principal Executive Officer)

March 30, 2015

/s/ Robert W. Cook
Robert W. Cook
Chief Financial Officer
(Principal Financial Officer)

March 30, 2015

* A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to MELA Sciences, Inc. and will be retained by MELA Sciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This written statement accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and will not be incorporated by reference into any filing of MELA Sciences, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, irrespective of any general incorporation language contained in such filing.