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, 2013

☐ **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 ☒

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 42,721,456 shares of common stock held by non-affiliates of the registrant as of June 28, 2013 was $39,730,954 based on the last reported sale price of $0.93 per share on the Nasdaq Capital Market on June 28, 2013. (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 0.9% 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 February 28, 2014 was 47,755,791 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2014 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.

2013 FORM 10-K ANNUAL REPORT
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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 focused on the commercialization of our flagship product, MelaFind®, as well as 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. MelaFind® 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' on 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.

The components of the MelaFind® system include:

- a *hand-held component*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- our *proprietary database* of pigmented skin lesions, believed to be the largest positive 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, the Company received written approval from the U.S. Food and Drug Administration ("FDA") for the MelaFind® Pre-Market Approval ("PMA") application and in September 2011 received Conformite Europeenne ("CE") Mark approval for MelaFind®. On March 7, 2012, the Company installed the first commercial MelaFind® system, and proceeded with the commercial launch of MelaFind®. We are currently conducting a Post-Approval Study ("PAS") evaluating the sensitivity and false positive rate of physicians after using MelaFind®.

In 2012, the Company evolved from a research and development company to a commercial enterprise. The launch of MelaFind® in 2012, and the subsequent first phase commercialization activities did not meet the Company's initial goals and objectives. Revenues were lower than anticipated and expenses continued to increase throughout 2012 and into 2013. Our cash used in operating activities for the year ended December 31, 2013 and December 31, 2012 totaled $19.4 million and $19.2 million, respectively and net revenues totaled $0.5 million and $0.3 million, respectively.

In mid-2013, a significant cost reduction program was put in place. On November 11, 2013, a new CEO was brought on board and a newly refocused "Go-to-Market" strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma was adopted. As part of this strategy, in late December, we elected to change our business model from a rental to a sale model for the MelaFind® device. We have also begun 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 for use of the MelaFind® device. We anticipate that this process could take up to two years. Once a coverage determination has been made, we plan to seek reimbursement by Medicaid, Medicare and other third-party payers.

Skin cancer is the most common form of cancer in the U.S. More than 3.5 million skin cancers in over 2 million people are diagnosed annually. 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 fatalities and is the deadliest of all skin cancers. There currently is no cure for advanced stage melanoma. However, detection of early melanoma can lead to virtually a 100% cure rate. Advanced stage melanoma is costly to treat and is responsible for approximately 90% of the total spending on melanoma

treatment in the U.S., costing up to $160,000 per patient. If diagnosed early, however, melanoma is almost always cured by simple resection at a cost of approximately $4,500 per patient. The cost of treating a Stage IV melanoma is estimated to be more than 22 times the cost of treating a melanoma at the non-invasive "*in situ*" stage.

Melanomas are mainly diagnosed by dermatologists and/or primary care physicians using visual clinical evaluation. Physicians assess pigmented skin lesions using the "ABCDEPRU" criteria; Asymmetry, Border irregularity, Color variegation, Diameter greater than 6 mm, Evolving — change in "ABCD" over time, Patients concern, Regression and Ugly duckling. This assessment is subjective and results in missed melanomas as well as a highly variable ratio of benign lesions biopsied to melanomas detected. This biopsy ratio is as high as 50 to 1 for dermatologists and up to 80 to 1 for primary care physicians.

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 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, the deadliest form of skin cancer.

We believe that with the assistance provided by MelaFind®, dermatologists could diagnose more melanomas at the most curable stages with fewer false positive biopsies than would be achieved on their own at equal sensitivity levels, this would reduce both treatment cost and the number of biopsies on benign moles. Our goal is for MelaFind® to become 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, and is estimated to account for almost 50% of all cancers. 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 fatalities and is the deadliest of all skin cancers. It is estimated that more than 135,000 new cases of melanoma will be reported as having been diagnosed in the U.S. in 2013 — more than 61,300 non-invasive (*in situ*) and more than 76,690 invasive. Melanoma causes one death every hour of every day of the year in the U.S. There are three significant forms of skin cancer: basal cell, accounting for approximately 75% of skin cancer cases; squamous cell, approximately 20% of skin cancer cases; and melanoma, which accounts for an estimated 4% of skin cancer cases. Unfortunately, Melanoma is responsible for approximately 75% of all deaths from skin cancer. The American Cancer Society projects that 9,480 of the more than 12,000 skin cancer deaths in 2013 will be from melanoma. Melanoma places significant burdens on the healthcare system well beyond Medicare, as approximately 62% of melanomas and 45% of melanoma deaths occur prior to the age of 65.

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 tumor enters into lymphatic channels and newly formed blood vessels, potentially resulting in significant morbidity (illness) and mortality (death). 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 about 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. While there has been a 20% decline in cancer deaths since 1991, melanoma is one of 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

Our long term objective is for MelaFind® to become an integral part of the standard of care in melanoma detection. To achieve this objective we are continuing to refocus our current strategy by instituting changes from the initial launch strategy:

- *Establish MelaFind® in key institutions.* We have recently placed MelaFind® clinical units with some of the most prestigious pigmented skin lesion experts and institutions in the country. Our goal is to have the nationally recognized experts conduct clinical trials to provide us with more data, which will support publications, reimbursement and presentations at conferences.
- *Increase the number of abstracts, posters and clinical presentations at Dermatology Conferences.* Beginning with the Fall Clinic Conference in November 2013 and leading up to the 2014 American Academy of Dermatology Meeting, the Company has presented nine abstracts and posters. Additionally, we have conducted 4 Clinical Advisory sessions to obtain critical data/information for further development of MelaFind®.
- *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.* We are pursuing a Current Procedural Terminology (CPT) code and third party insurance coverage for MelaFind®. We have engaged an expert consultant to assist us in this area and will move forward with the process over the next 18-24 months.
- *Continue to improve User Interface (UI) and reliability of MelaFind®.* Based on feedback from physicians, we will continue to improve our User Interface (UI) with probability statistics in 2014, and eventually move to take our multi and spectral optical imaging to a 3D rendition. We will continue to improve reliability and customer experience with MelaFind®, including improvements to the Flap Shutter and a new monitor.
- *Move from a rental business model to a lease/sale business model.* During December 2013, we set up the infrastructure to allow dermatologists to buy their MelaFind® unit, which allows us to recognize revenue immediately upon the sale. More importantly it allows the dermatologists to depreciate the equipment over time, which is the more common business model for medical devices.
- *Focus selling efforts in key areas of the U.S. and Germany.* Our team of sales representatives have refocused on targeted areas of the U.S. where key institutions (mentioned above) are located, and/or where the concentration of high risk patients is very high (Texas, Florida, New York, Boston, California, Cleveland, Chicago).

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. In contrast, MelaFind® delivers an objective assessment based on numerical scores assigned to the clinically atypical skin lesion under evaluation. Furthermore, clinical examination is limited to the surface appearance of the clinically atypical pigmented skin lesion, whereas MelaFind® utilizes 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. Although dermoscopy provides more information than unaided visual examination, mastery of the technique necessitates many years of training and experience. Proper use of dermoscopy can reduce the number of biopsies of benign lesions, but even experts in dermoscopy biopsy 3-10 benign lesions for every melanoma detected. While many primary care physicians immediately refer patients with clinically atypical pigmented skin lesions to a specialist, an increasing number perform biopsies on skin lesions themselves. This results in a ratio of benign lesions biopsied to confirmed melanomas of up to 80 to 1.

MelaFind® Product Description

MelaFind® is a non-invasive system to aid in the detection of melanoma. The MelaFind® system produces a report at the point-of-care to assist in the diagnostic process. MelaFind® employs light of multiple wavelengths to obtain data from clinically atypical lesions; and then the data are analyzed against our proprietary database of melanomas and benign lesions using our sophisticated algorithms. The MelaFind® report contains objective information about the lesion that may not be otherwise available, including information useful in making the decision whether to biopsy the lesion. The key components of the MelaFind® system are:

A hand-held component, which is comprised of several components:

- an illuminator that shines light of 10 different specific wavelengths, including near infra-red bands;
- a lens system composed of nine elements that focuses the light reflected from the lesions;
- a photon (light) sensor; 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 component. 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; (2) optimization of the mathematical formulas to differentiate benign lesions from melanoma; and (3) expansion of the size and diversity of our proprietary lesion database. The performance of future lesion classifiers is directly related to the size of the database used in classifier development, as well as the degree to which the training database is representative of the lesions that will be evaluated by MelaFind® in a practice setting.

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® 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 would be 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 greater than 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 physicians 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).

In order to generate a comparison with physicians' ability to accurately detect melanomas, the Company conducted an online reader study in which 155 physicians participated including 110 dermatologists. Using images and clinical histories for 65 randomly selected melanomas from the pivotal study, this group of dermatologists, on average, missed (i.e., would not have elected to biopsy) 28% of the melanomas. The biopsy sensitivity of MelaFind was 97% ($p < 0.0001$ versus dermatologists). In addition, the kappa score of dermatologists was 0.29, indicating only "fair agreement".

Hardware and Software History

ASKION GmbH ("ASKION"), 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 placement. ASKION also supports our R&D and design engineering activities with respect to MelaFind®. Nexcore Technologies, Inc. ("NEXCORE"), located in Waldwick, NJ, USA, continues to provide the Company with design for manufacture production engineering support of the MelaFind® cart assemblies.

The Company has obtained Underwriters' Laboratories ("UL") certifications as related to environmental and product safety and Certification Bodies' Scheme ("CB") test certification for MelaFind®. The Company has 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 the Company's R&D/Product Development Group at its facility located in Irvington, NY.

Post-Approval Study

In November 2011, the Company received written approval from the FDA for the MelaFind® PMA. The Company committed to conduct a Post-Approval Study ("PAS") of MelaFind® as a condition of PMA approval. Agreement with the FDA on the study protocol was reached and the study was initiated during 2012. Under the terms of the agreement, the Company is 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, the second was submitted on August 8, 2013 and the third report was submitted on February 8, 2014. The Company anticipates that the PAS could be costly and time consuming to complete.

On October 17, 2013, the FDA sent the Company a letter stating the information in its August 8, 2013 progress report with respect to the PAS was inadequate to allow the agency to complete its review and therefore the FDA asked for additional information. Because of rate of accrual issues, the FDA's letter informed the Company that the study status was revised on the FDA's website to "Progress Inadequate." On September 9, 2013, the Company placed this study on hold to investigate enrollment. On November 15, 2013, the Company responded to the FDA's letter, outlining an enrollment plan as well as a new enrollment schedule. On January 2, 2014, the FDA prompted an interactive review process to obtain further additional information regarding the Company's response. On January 13, 2014, the enrollment plan and enrollment schedule was approved by the FDA and the interactive review process was closed as the FDA deemed the Company had sufficiently met the reporting expectations of the report. The new study timeline was approved for study restart in January 2014 and steps to restart the study have been initiated.

Our Reimbursement Strategy

We are in the process of pursuing a CPT code and private insurance coverage. We are aware of no CPT code that is specifically applicable to the use of MelaFind®. We have engaged the services of expert consultants with extensive experience in the CPT, coverage and payment decision processes to assist us in this strategy.

In the U.S., healthcare providers that utilize medical systems such as MelaFind® generally rely on third-party payers, including Medicare, Medicaid, private health insurance carriers, and managed care organizations, to reimburse part, but not necessarily all of the costs and fees associated with the procedures performed using these devices. Public and professional concern about the cost of medical care and new technologies has evoked a variety of remedies. Third-party payers are increasingly challenging the pricing of medical products and procedures. Guidelines have been established that recognize the need for clinical strategies to assess the cost-effectiveness of new diagnostic tools or procedures, in the hope of reducing the variations in diagnostic and treatment protocols and reducing healthcare expenditures. Insurers are also attempting to curb over utilization by applying a rational analysis of the costs versus benefits of new technologies.

It is critical to build a sufficient body of evidence to support favorable coding and coverage decisions and to secure appropriate levels of payment from third-party payers. It is our intent to submit an application for a new CPT code to the American Medical Association ("AMA") CPT Editorial Panel pursuant to the establishment of significant clinical evidence to support favorable coding and coverage decisions. If the CPT Editorial Panel concurs that a new CPT code is needed and appropriate, and we are able to demonstrate that MelaFind ® is reasonable and necessary for the Medicare population, we would expect that the new code would be referred to the AMA's Relative Value Scale Update Committee ("RUC") to determine the appropriate level of Medicare Part B reimbursement for the procedure, relative to other physician services. This analysis would include a survey of physicians utilizing MelaFind ® in the practice setting. In setting Medicare reimbursement rates, CMS is generally guided, though not bound, by the recommendation of the RUC. Medicare coverage and payment policies significantly influence the practices and policies of private payers, managed care organizations, and state Medicaid agencies. We would expect to commence efforts to obtain positive coverage decisions from private payers, managed care organizations, Medicaid agencies, and state Medicare administrative contractors pursuant to the establishment of significant clinical evidence to support favorable coding and coverage decisions and secure appropriate payment levels at a future date.

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 ® will represent an improvement in the standard of care for the detection of melanoma. As such, we anticipate that its adoption by physicians and reimbursement by payers will be facilitated by medical and scientific evidence published in peer-reviewed journals and presentations at scientific and medical meetings. We plan to execute a publication strategy and to provide information for continuing medical education efforts in order to communicate the potential of MelaFind ® to improve patient care. In addition to the PAS, we have also designed and plan to implement clinical trials in order to evaluate MelaFind® in the clinical setting. These studies will include research studies as well as reader studies to investigate the potential use of MelaFind® in identifying "ugly duckling lesions" in patients with multiple nevi as well as to investigate the impact of MelaFind® on a dermatologist's decision to biopsy a suspicious pigmented skin lesion in a clinical setting. We anticipate that the results of these studies will also be published in peer-reviewed journals and presented at scientific and medical meetings and that these studies will help to demonstrate the potential of MelaFind ® to improve patient care.

We recognize that a favorable reimbursement environment could have a significant impact on MelaFind®'s adoption and commercial success. Even if a procedure is eligible for reimbursement, the level of reimbursement may not be adequate. 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. We have anticipated this need and we have begun to employ an active strategy to obtain medical coverage, identify appropriate coding and establish adequate payment.

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.

Whole Body Mole Mapping Systems—Whole body mole mapping consists of periodic photography of patients, typically those at high risk for developing melanoma. The pictures are reviewed clinically. This service is provided at some diagnostic imaging centers and dermatology offices. One company we are aware of offers a computerized system for acquisition, storage, and review of the pictures, while another company offers a similar sequential photography system.

Dermoscopes—Dermoscopy, or epiluminescence microscopy, allows for non-invasive visualization of colors and microstructures of the epidermis, the dermal-epidermal junction, and the papillary dermis not visible to the naked eye. Manufacturers of dermoscopes include (but are not limited to) Welch Allyn, Inc. (U.S.), Heine Optotechnik (Germany), Riester Medical (Germany) and 3Gen, LLC (U.S.) Also, we believe that several manufacturers are selling apps and hardware that allow an Apple iPhone to be used as a dermoscope.

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. The system, integrates non-harmful light and digital imaging to evaluate lesions in five distinct views. This software produces a rating "score" for scanned lesions.

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 (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 in less than a second.

Newly Identified Light-Based Approaches—We are aware of two companies that are developing technologies utilizing these newly identified light-based 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 is developing 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 we are aware of is exploring Messenger RNA analysis of surface cells. Its core technologies are 1) a patented, non-invasive technique that uses an adhesive to painlessly 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 are currently focusing our manufacturing efforts with our contract manufacturers on building MelaFind® systems with reduced labor and material costs through optimizing testing efficiencies, latest product improvements and utilizing additional second tier value-added component suppliers.

To support our commercialization of MelaFind®in the European Union, we have contracted with ASKION in Germany, an ISO 13485 certified manufacturer, which specializes in precision optics. ASKION also performs the system integration of the MelaFind® hand-held, cart assemblies and operating system software to support MelaFind® system placements in Europe.

ASKION is the company's authorized EU Representative and provides sales & marketing support, technical field service, system installation, product repair activities, warehousing and distribution for our European market place. ASKION additionally supports our EU regulatory commitments working in conjunction with the Company's registrar BSI as related to our CE Mark certification. To support our commercialization of MelaFind®in the USA, we have also contracted NEXCORE Technology Inc., an ISO 13485 certified manufacturer of medical devices in New Jersey, to provide the assembled MelaFind® cart assemblies. NEXCORE also performs the system integration of the MelaFind® hand-held, cart assemblies and operating system software to support MelaFind® system placements in the U.S.

Additionally, NEXCORE supports the company with warehousing and product related service & repair activities for our U.S. market place.

Research and Development Efforts

We continue to develop refinements and improvements to the hardware and software of MelaFind®, including updated lesion classification algorithms, using the latest techniques, some of which may require approval of a PMA supplement. Our research and development ("R&D") plan also includes further improvements such as faster and easier software downloads for future versions.

We are currently working towards reducing our cost of goods, along with improving the customer experience, through several hardware improvements. The most notable improvement is the use of an internal reference target within the hand-held imager to replace our current phantom target imaging system calibration test. Also to reduce the cost of goods, we plan to use an off-the-shelf solution to replace our current highly customized cart. We are also addressing reliability issues through improved monitors, and planned field upgrades to our existing hand-held imagers.

A new user interface is nearing completion. Based on physician feedback, it will include a probability score relative to our pivotal trial data to assist the physician with explaining the MelaFind® scores to the patient.

We have begun development of a multi-spectral 3D display technique, intended to improve information transfer to the dermatopathologist regarding specific suspicious areas within the excised lesion. The intent is to improve efficiency when creating slides for final diagnosis. Additionally, our 3D imaging technique is aimed at assisting the surgeon with biopsy, providing additional information to assist with margin guidance, similar to other image guided biopsy techniques. We are planning on a 510(k) submission for the commercial release of the 3D imaging system.

The Company spent approximately $6.8 million and $3.8 million in 2012 and 2013, respectively, on R&D. With the commercial launch of MelaFind®, certain costs previously included under R&D, such as costs associated with the PAS, will in the future be recorded as general and administrative costs. R&D efforts going forward will focus on refinements to MelaFind® as well as new, complementary technology.

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. Currently, we have twenty-three issued U.S. patents in force, and one more that is projected to issue in 2014, and these patents have numerous foreign counterparts issued and pending. Of those issued, eighteen U.S. patents, six 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. In addition, we have three U.S. utility patents currently pending, all of which relate to MelaFind®. Of the many pending foreign patent applications that relate to MelaFind ®, six are currently in the European regional phase (with the European Patent Office), four are pending in Australia, six in Canada, one in Japan, and three in Hong Kong. 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 which 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 active U.S. trademark registrations for the word marks: MELA, MELA SCIENCES, MELAFIND, MELAFINDER and MELARECORD, as well as for the stylized MELA Sciences logo, and for two forms of our "MelaFind®" word-plus-design (logo) mark. The "MELA," "MELA SCIENCES," "MELAFIND" and "MELARECORD" word marks are currently registered in the European Union and Australia, and "MELAFIND" also registered in New Zealand. (Any combinations of upper- and lower-case letters in any style or color, are covered by "standard character" word mark registrations, indicated here by upper-case lettering.) For the "MELA Sciences" logo, the U.S. registration in International Class 10 is for: "medical devices, namely, electro-optical devices incorporating both hardware and software for obtaining images in different spectral bands and software for analyzing the images for use in analyzing skin lesions and determining the existence of melanoma; instrumentation comprising computer-assisted optical images and image analyzers for use in the detection of cutaneous melanoma and other pathology of skin and tissues" as well as in International Class 16 for: "printed materials, namely, medical reports, and instructional and teaching materials, all related to the detection and analysis of cutaneous melanoma." For the "MELAFIND" word mark and the "MelaFind" logos, the descriptions of goods covered by the U.S. registrations in International Class 10 are similar to that cited above. The recently awarded U.S. registration for our short-height "MelaFind" logo also covers "prerecorded magnetic, electronic and optical storage media for which users can also add images, data and text, all in the field of the diagnosis and treatment of cutaneous melanoma and other pathology of the skin and tissues, in class 9", as well as printed materials in International Class 16, as described above. In Europe, besides International Class 10, the "MELAFIND" word mark is also registered in International Classes 16 (for printed reports) and 44 (as a service mark). The "MELARECORD" word mark is registered in classes 9, 10 and 16 in the U.S., the European Union, and Australia. The registration in class 9 covers the "Electronic MelaRecord®" Patient Card, while the registration in class 16 covers printed reports for patients, physicians or pathologists, for example. The registration in class 10 covers the "MelaRecord® auxiliary card reader," for example. The "MELAFINDER" service mark is registered in International Class 42, for: "Providing a website featuring a search engine for locating dermatologists using specialized melanoma detection equipment." Additional trademark registrations are pending in the U.S. for which no Statements of Use have yet been filed; those marks include "MELAFIND MOLE" (in classes 16 and 44) and "OID" (in classes 10 and 16), as standard character marks.

We also have registered the internet domain names: www.melasciences.com, www.eosciences.com, www.melafind.com, www.mela.us.com, www.melafind.info, www.melafind.net, www.melafind.org, www.melafind.us, www.melafinder.com, www.melainc.com, www.skinsurf.com, www.melafind.eu, www.melafindtraining.com, www.projectmelanoma.com, www.projectmelanoma.org, and www.iknowmelanoma.com.

The following table lists our U.S. patents and patent applications relating to melanoma detection:

U.S. Patents Relating to MelaFind®

Patent #	Title	Issued	Expiration
6,081,612	Systems and Methods for the Multispectral Imaging and Characterization of Skin Tissue	06/27/00	02/27/18
6,208,749	Systems and Methods for the Multispectral Imaging and Characterization of Skin Tissue	03/27/01	02/27/18*
6,626,558	Apparatus for Uniform Illumination of an Object	09/30/03	08/31/21
6,657,798	Method for Optimizing the Number of Good Assemblies Manufacturable From a Number of Parts	12/02/03	02/10/23
6,710,947	Method for Assembling Lens Elements	03/23/04	02/27/23
7,102,672	Integrated CMOS Imaging Array & Dark Current Monitor	09/05/06	01/10/24
7,127,094	Method of Controlling Data Gathered at Remote Locations	10/24/06	03/10/25
D613,866	Medical Cart	04/13/10	04/13/24
D613,867	Table Structure of a Medical Cart	04/13/10	04/13/24
7,813,586	Reducing Noise in Digital Images	10/12/10	05/31/27
7,894,651	Quantitative Analysis of Skin Characteristics	02/22/11	11/24/29
8,160,386	Reducing Noise in Digital Images (CIP)	04/17/12	08/07/26
8,208,698	Characterizing a Texture of an Image	06/26/12	04/25/31
8,286,977	Medical Cart	10/16/12	10/25/30
8,381,987	An Insertable Storage Card Containing a Portable Memory Card Having a Connection Interface	02/26/13	06/29/30
8,433,116	Showing Skin Lesion Information	04/30/13	09/16/31
8,452,063	Showing Skin Lesion Information (CIP)	05/28/13	05/30/31
8,630,508	Reducing Noise in Digital Images (CIP #2)	01/14/14	08/07/26

* A post-PMA request for patent term extension under the Hatch-Waxman Act was filed 12/19/11 and is still pending.

Pending Non-Provisional U.S. Patent Applications Relating to MelaFind®

Published Pat Appl Ser #	Title	Filed
US2008/0312952A1	Regulating Use of a Device to Perform a Procedure on a Subject	06/12/07
US2009/0060304A1	Obtaining Dermatology Information	09/04/08
US2012/0033863A1	Assessing Features for Classification**	08/06/10
US2013/0242118A1	Showing Skin Lesion Information (CIP #2)	04/23/13

Note: CIP denotes a Continuation-in-Part patent application.

** Notice of Allowance with Patent Term Adjustment of 294 days was issued 12/10/13

Patent No. 6,081,612 relates to the MelaFind® system and methods employed in building MelaFind® classification algorithms involving the use of novel multi-spectral lesion features by means of wavelet maxima representations. Wavelet maxima representations use specific types of mathematical transformations called wavelets to represent a signal, such as digital data of a lesion taken by the MelaFind® system, at different detail levels. The wavelet maxima representation retains information of potential diagnostic value. This information is quantified in the form of statistical features used for automatic classification. Patent No. 6,208,749 relates to methods employed for automatic segmentation of the lesion digital data, and in building MelaFind ® classification algorithms involving the use of novel features of multispectral lesion data that do not involve the use of wavelet transformations, to determine whether the lesion is or is not a melanoma. We believe the inclusion of the described wavelet and non-wavelet features improves significantly the sensitivity and specificity of the melanoma classifiers.

Patent No. 6,626,558 covers the construction of the array of numerous light-emitting diodes ("LED's") that are used in the MelaFind® hand-held device to provide uniform illumination of lesions in multiple spectral bands of illumination. Patent No. 6,657,798 involves the use of a computer algorithm to optimize the number of good lens assemblies possible from a given number of sets of lens elements. Patent No. 6,710,947 describes a method that we may employ for the economical assembly of the nine elements of the MelaFind® hand-held device's optical lens module.

Patent No. 7,102,672 covers a process that we may employ to compensate for the effect of temperature-dependent dark current on the data acquired by the MelaFind® hand-held probe, and Patent No. 7,127,094 covers a series of methods for central control of the acquisition and processing of the data acquired by MelaFind® probes located at remotes sites. Patent No. 7,813,586 covers a novel method for reducing noise in digital data, which was invented and has been implemented as part of the calibration of all MelaFind® image digital data. Six more claims are covered in its Continuation-in-Part Patent No. 8,160,386, while 21 additional claims are covered in its further Continuation-in-Part Patent No. 8,630,508. The two design patents describe novel design aspects of the first commercial MelaFind® medical cart, while Patent No. 8,286,977 protects certain innovative functional aspects of that cart. Patent No. 8,381,987 covers 20 claims for "An Insertable Storage Card Containing a Portable Memory Card Having a Connection Interface," which protect certain aspects of the MelaRecord® Patient Card used with MelaFind®. Our June 12, 2007 patent filing relates to innovative ways to control use of our MelaFind® system, such as via the Patient Card. Our September 4, 2008 patent filing concerns certain dermatology information associated with MelaFind® and claims priority to a provisional application filed a year earlier.

Patent No. 7,894,651 protects devices and methods for quantitative analysis of skin characteristics to identify lesions that require further evaluation by physicians to rule out melanoma. Patent No. 8,208,698 relates to new methods for characterizing the "lacunarity" texture of an image. Patent Number 8,433,116 ("Showing Skin Lesion Information") covers 46 claims relating to the MelaFind® user interface, and its Continuation-in-Part Patent Number 8,452,063 covers 19 additional claims regarding the user interface. Still further claims for the user interface are pending in the Continuation-in-Part patent application filed on April 23, 2013.

On December 10, 2013, a Notice of Allowance was issued for 23 claims on the patent application filed August 6, 2010 which discloses a novel method of "Assessing Features for Classification" for use in generating lesion classifiers such as those employed for the MelaFind® device. Because of extensive delays by the U.S. Patent and Trademark Office, the patent term will be extended by at least 294 days.

We also 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 a number of 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

Our product, MelaFind®, is regulated as a medical device and is subject to extensive regulation by the FDA and other regulatory authorities in the U.S. 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.

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.

PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

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 the Company 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 any of the following sanctions:

- 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 our MelaFind® product is subject to both FDA and Federal Trade Commission regulations. 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, 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.

The Company successfully achieved the ISO 13485 certification for the design and development of medical devices through its international registrar, BSI. In September 2011, after review and approval of the MelaFind® technical file, the Company 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 and 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, 2013, we had 45 full-time and 5 part-time employees, of whom 15 were engaged in research and development, 12 in production (including clinical, regulatory affairs, document control and quality assurance) and 23 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. 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 and development relating to MelaFind®. Our net loss for the year ended December 31, 2013 was approximately $25.9 million and as of December 31, 2013, we had an accumulated deficit of approximately $168.1 million. Our expenses will increase in connection with our continued commercialization and development activities related to MelaFind®. Having commenced commercialization in March 2012, we expect to incur additional medical, marketing and sales expenses in the near future and to incur additional contract manufacturing and inventory expenses in the future which will require additional funding. Furthermore, having recently commenced a refocused marketing strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma, we expect to incur additional expenses continuing to transition our operations and implementing our refocused marketing strategy. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future and cannot determine at this time when we will generate any significant revenues. These 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 17, 2014 on our financial statements for the period ended December 31, 2013, 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 be unable to continue commercialization and continue development of MelaFind® enhancements or other products without additional funding.

As of December 31, 2013, we had approximately $3.8 million in cash and cash equivalents and cash used in operations for the year ended December 31, 2013 was approximately $19.4 million. Our total liabilities at December 31, 2013 were approximately $5.8 million. We expect to incur significant losses for the foreseeable future and may not achieve operating profits or positive cash flows from operations. Furthermore, under the terms of our recently completed financing of our Series A Convertible Preferred Stock, we are prohibited from selling any shares of our common stock or securities convertible into shares of common stock until the later of July 31, 2014 or 2 months after the re-sale registration statement we are required to file in connection with this offering is declared effective by the SEC. The Company's ability to fund its 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 the Company may require will be affected by the commercial success of its 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 transitioning our operations and implementing a refocused 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 the Company's 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 and 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.

We may have to pay liquidated damages of $3.9 million to the investors in our recent financing of Series A Convertible Preferred Stock.

In February 2014, we sold an aggregate of 12,300 shares of our 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 14,642,857 shares of our common stock at an initial conversion price of $0.84, and warrants to purchase up to 13,297,297 shares of our common stock for aggregate gross proceeds of $12.3 million to three institutional investors (the "Purchasers"). In connection with this financing, we granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Series A Preferred Stock and the warrants pursuant to the terms of a Registration Rights Agreement. In addition to the registration rights, the Purchasers are entitled to receive liquidated damages upon the occurrence of a number 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 of the Company to file a resale registration statement by no later than February 25, 2014 and the failure of the Company to have such resale registration statement declared effective by the Securities and Exchange Commission by no later than March 7, 2014. The liquated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquated damages payable is equal to 10% of the aggregate purchase price paid by each Purchaser for the first two events (and/or the monthly anniversary of an event), 7.5% of the aggregate purchase price paid by each Purchaser for the third event (and/or the monthly anniversary of an event), 2.5% of the aggregate purchase price paid by each Purchaser for the fourth event (and/or the monthly anniversary of an event), and 1% of the aggregate purchase price paid by each Purchaser for the next two events (and/or the monthly anniversary of an event), in all up to a total of 32% of the aggregate purchase price paid by each Purchaser. The liquidated damages are prorated on a daily basis for each event until such event is cured. We have already paid liquidated damages to the Purchasers in the amount of $2.5 million and may have to pay additional $1.4 million liquidated damages to the Purchasers.

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 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 adaption 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 refocused 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
- 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 Post-Approval Study evaluating the sensitivity and false positive rate of physicians after using MelaFind® to their performance if MelaFind® was not available. Conducting this Post-Approval Study 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, the second was submitted on August 8, 2013 and the third report was submitted on February 8, 2014. 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 March 4, 2013 and October 17, 2013, the FDA sent a letter stating that the information in our progress report was

inadequate to allow the agency to complete its review and therefore the FDA asked for additional information. We responded to the March 4, 2013 letter on March 22, 2013 and the October 17, 2013 letter on November 15, 2013. We placed the study on hold on September 9, 2013 to investigate enrollment issues and make protocol clarifications. An interactive review process was initiated by the FDA on January 2, 2014, requesting additional information beyond our October 17, 2013 response letter to 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 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.

The FDA posts information about the status of post-approval studies on its website. These website postings could undermine the credibility of the Company or MelaFind®, or have other collateral effects. For example, the agency will identify the study status as "Progress Inadequate" if the study progress is inconsistent with the protocol, such as if the study is not meeting the enrollment schedule, if the study is missing timepoint evaluations, if there are poor follow-up rates, or if not all the endpoints are evaluated. Because of rate of accrual issues, the FDA's October 17, 2013 letter informed us that our study status was revised on the FDA's website to "Progress Inadequate." On January 13, 2014, while closing our interactive review process, the FDA approved a study restart of January 2014 and informed us that the "Progress Inadequate" status would not be revised until the study hold is removed. Due to weather related delays affecting our protocol review meeting with the FDA, the study was restarted February 25, 2014 following an interactive preliminary protocol review with the agency. Our next report is due to the FDA in August 2014.

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 us or that the reimbursement we do obtain will be adequate for us to maintain 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. We believe that other products that enhance the visualization and analysis of potential melanomas have been approved 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 refocused 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 refocused 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. Each of these suppliers is a sole-source supplier. Our contract suppliers also 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 of 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.

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act. The legislation 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 the Company does provide off-site back-up for its 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 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 6.9 and 4.3 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 13.3 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.

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. We currently do not have a Chief Financial Officer and our Controller is serving as our principal financial officer on an interim basis until we hire a Chief Financial Officer. We are currently engaged in a search for a new Chief Financial Officer.

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.

New regulations related to conflict minerals may adversely affect us.

The SEC recently adopted disclosure rules for companies that use conflict minerals in their products, with substantial supply chain verification requirements in the event that the materials come from, or could have come from, the Democratic Republic of the Congo or adjoining countries. These new rules and verification requirements, which will apply to our activities in calendar 2013, will impose additional costs on us and on our suppliers, and may limit the sources or increase the prices of materials used in our products. Further, if we are unable to certify that our products are conflict free, we may face challenges with our customers, which could place us at a competitive disadvantage, and our reputation may be harmed.

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 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.

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

On August 22, 2013, we received a notice from The Nasdaq Stock Market that for the previous 30 consecutive business days, we were not in compliance with a Nasdaq rule for continued listing that requires a listed company's common stock to maintain a minimum bid price of $1.00 per share. We were granted an automatic 180 grace period by Nasdaq in which to regain compliance. On February 19, 2014, we were notified by Nasdaq that the Company was eligible for an additional 180 day grace period and has until August 18, 2014 to regain compliance with Nasdasq's minimum bid price requirement. 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;
- 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.

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 under the symbol MELA. Prior to such time, 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, 2012 through December 31, 2013 as reported by the NASDAQ Capital Market:

	High	Low
Year Ended December 31, 2013		
October 1—December 31, 2013	$ 1.04	$ 0.63
July 1—September 30, 2013	$ 1.07	$ 0.65
April 1—June 30, 2013	$ 1.39	$ 0.70
January 1—March 31, 2013	$ 2.19	$ 1.08
Year Ended December 31, 2012		
October 1—December 31, 2012	$ 3.35	$ 1.71
July 1—September 30, 2012	$ 4.37	$ 3.01
April 1—June 30, 2012	$ 4.87	$ 2.50
January 1—March 31, 2012	$ 5.13	$ 3.19

As of January 31, 2013, there were approximately 166 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 12/31/2013	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	3,065,714	$ 1.62	3,729,853
Equity compensation plans not approved by stockholders	—	—	—
Total	3,065,714	$ 1.62	3,729,853

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, 2013 and the related notes appearing in Part II Item 8 of this report.

Overview

We are a medical device company focused on the commercialization of our flagship product, MelaFind®, the further design and development of MelaFind® and our technology. MelaFind® is a non-invasive, point-of-care instrument to aid in the detection of melanoma. MelaFind®, features a hand-held component that emits multiple wavelengths of light to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated classification algorithms, "trained" on our proprietary database of melanomas and benign lesions. This then provides information to assist in the management of the patient's disease, including information useful in the decision whether to biopsy the lesion.

In November 2011, the Company received written approval from the FDA for the MelaFind® PMA application and in September 2011 received CE Mark approval for MelaFind®. On March 7, 2012, the Company installed the first commercial MelaFind® systems, and proceeded with the commercial launch of MelaFind®. We are currently conducting a Post-Approval Study ("PAS") evaluating the sensitivity and false positive rate of physicians after using MelaFind® to their performance if MelaFind® was not available.

In 2012, the Company evolved from a research and development company to a commercial enterprise. The launch of MelaFind® in 2012, and the subsequent commercialization activities following the launch did not meet our initial goals and objectives. Revenues were lower than forecasted and expenses continued to increase throughout 2012 and into 2013. Our cash used in operating activities for the year ended December 31, 2013 and December 31, 2012 totaled $19.4 million and $19.2 million, respectively and net revenues totaled $0.5 million and $0.3 million, respectively.

In mid-2013, a significant cost reduction program was put in place. On November 11, 2013, a new CEO was brought on board and a newly refocused "Go-to-Market" strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma was adopted. As part of this strategy, in late December, we elected to change our business model from a rental to a sale model for the MelaFind® device. We have reduced our costs, brought new and experienced talent to our management team and have reconsidered the approach to the commercialization of the MelaFind® device. We have also begun the process of obtaining a coverage determination from the Centers for Medicare & Medicaid Services, the federal agency that administers Medicare, in order to obtain reimbursement by Medicare for use of the MelaFind® device. We anticipate that this process could take up to two years. Once a coverage determination has been made, we plan to seek reimbursement by Medicaid, Medicare and other third-party payers.

Our revenue for the foreseeable future will depend on the success of MelaFind®, and may vary substantially from year-to-year and quarter-to-quarter. Our operating expenses may also vary substantially from year-to-year and quarter-to-quarter. We believe that period-to-period comparisons of our results of operations may not be meaningful and should not be relied on as indicative of our future performance.

We commenced operations in December 1989 as a New York corporation and re-incorporated as a Delaware corporation in September 1997. Since our inception, we have generated significant losses. As of December 31, 2013, we had an accumulated deficit of approximately $168.1 million. We expect to continue to spend significant amounts on the commercialization of MelaFind®.

Subsequent to year end, we raised approximately $11.5 million in net proceeds from the private placement of convertible preferred stock, common stock warrants and common stock. As of March 7, 2014, we paid a total of $2.5 million and may be required to pay an additional $1.4 million in liquidated damages to the investors in this private placement as a result of our failure to file and have declared effective a registration statement in accordance with the time periods set forth in a registration rights agreement between us and the investors. We believe, even with cash and cash equivalents held at December 31, 2013, and cash raised subsequent to year end, that there is significant doubt about our ability to continue as a going concern. We continue to assess the effects of our previously announced cost reduction plan and are prepared to reduce various operational costs. Should the Company experience unforeseen expenses, or if anticipated revenues are not realized, the effect could have a further negative impact on management's estimated operating results over the next twelve months. The timing and amount of any additional funding the Company may require will be affected by the commercial success of Melafind®. The funding could be in the form of either additional equity or debt financing. Most of our expenditures to date have been for research and development activities and general and administrative expenses. Research and development expenses represent costs incurred for product development, clinical trials and activities relating to regulatory filings and manufacturing development efforts. We expense all of our research and development costs as they are incurred.

Our research and development expenses incurred for the year ended December 31, 2013 were related primarily to the development of MelaFind®. We expect to continue to incur certain additional research and development expenses relating to MelaFind®. Additional research and development charges may be incurred for complementary technologies. These additional expenses could exceed our estimated amounts, possibly materially.

Selling, general and administrative expenses consist primarily of salaries and related human resources expenses, legal expenses, general corporate activities and costs associated with our efforts to expand our commercial infrastructure to market and sell MelaFind®. At December 31, 2013, we had available income tax benefit from net operating loss carryforwards for federal income tax reporting purposes of approximately $87.0 million. The net operating loss carryforwards may be available to offset future taxable income expiring at various dates through the year 2032. The Company's ability to utilize its net operating losses may be significantly limited due to future changes in the Company's ownership as defined by federal income tax regulations.

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 U.S. 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.

During 2013, we generated revenue from usage based on the number of patient sessions, lesions examined, or a fixed monthly fee. Electronic record cards activate the MelaFind ® system, capture data and store the data for each patient visit. Additionally, 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, we allocate total contract consideration to each element based upon the relative standalone selling prices of each element, and recognize 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 we make 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 and a per patient usage charge. Revenue generated from German contracts is recognized when earned.

In December 2013, the Company changed its business model from a rental and usage model, to a sales model for our MelaFind ® product.

Property and Equipment

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.

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 exceeds 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.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service where we have 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, our estimates are most affected by our projections of the timing of services provided relative to the actual level of services provided by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. 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. We make these judgments based upon the facts and circumstances known to us and accrue for such costs in accordance with accounting principles generally accepted in the U.S. This is done as of each balance sheet date in our financial statements.

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" 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.

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 6,857,142 common stock warrants issued in connection with the October 31, 2013 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, 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, and any change in fair value is recognized in the Company's statements of operations. The fair value of warrants issued by the Company in connection with the transaction has been estimated using a Black-Scholes valuation. We also accounted for 693,202 common stock warrants that were issued in connection with our debt financing, as a liability until we increased our authorized number of shares at the 2013 Annual Meeting of Stockholders and then reclassed it into equity. We recorded a change in fair value over that period of approximately $.09 million.

Recently Issued Accounting Standards

The Financial Accounting Standards Board ("FASB") periodically issues new accounting standards in a continuing effort to improve standards of financial accounting and reporting. We have reviewed the recently issued pronouncements and concluded that there are no recently issued accounting pronouncements that the Company has yet to adopt that are expected to have a material effect on the Company's financial position, results of operations or cash flows.

Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

Revenue

Revenue was $0.5 million for the year ended December 31, 2013 as compared to revenue of $0.3 million for the year ended December 31, 2012, an increase of $0.2 million. This increase is the result of an increase in placement fees and system usage. In general, under the Company's previous rental model with respect to placement of MelaFind® systems, the Company signed a user agreement with its customers that usually included an installation fee for the placement of the MelaFind® system and provided for the billing of usage based on the number of patient sessions or lesions examined, or a fixed monthly rental fee. In addition, the user agreement provided for the sale of consumables needed to operate the system. Deferred revenue primarily reflects the timed recognition of the installation fee revenue over the term of the user agreement, which is generally two years.

Cost of Revenue

Costs of revenue were $4.3 million for the year ended December 31, 2013 as compared to $2.0 million for the year ended December 31, 2012, an increase of $2.3 million. Costs of revenue were primarily made up of direct costs associated with the placement of the MelaFind® system in the doctor's office, the cost of consumables delivered at installation, the cost of the electronic record cards, technical support costs and depreciation expense of the MelaFind® system placed with the customer, which under the Company's previous rental model with respect to placement of MelaFind® systems, remains the property of the Company. Certain product quality and manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind® are allocated to costs of goods sold. The Company had not recorded any cost of revenue prior to the commercial launch of MelaFind®.

Research and Development Expense

Research and development ("R&D") expenses decreased 44% to approximately $3.8 million for the year ended December 31, 2013 as compared to $6.8 million for the year ended December 31, 2012. The decrease is the result of resources being redeployed from R&D activities to supporting product revenue and the cost reduction plan initiated in August 2013, offset by reorganization costs. Ongoing R&D efforts are for product enhancements.

Selling, General and Administrative Expense

Selling, general and administrative ("SG&A") expenses increased $1.3 million or 9% to approximately $15.5 million for the year ended December 31, 2013 as compared to $14.2 million for the year ended December 31, 2012. The increase is the result of increases in professional fees in connection with debt and equity financings and an increase in severance expense due to the resignation of certain executive officers during the year ended December 31, 2013.

Impairment of Long-lived Assets

During year ended December 31, 2013, our marketing shifted focus to large cancer centers and high risk patients, and we have taken an impairment charge of approximately $1.0 million against our MelaFind® systems previously placed in locations that do not fit this profile. However, as these user agreements expire over the next 2 years, we anticipate that the affected systems will be redeployed in some capacity.

Interest (Income)/Expense

Interest income for the year ended December 31, 2013 decreased to $.008 million from $.03 million for the comparable period of 2012. Interest income decreased primarily as a result of smaller cash balances during the period in 2013.

Interest expense increased $0.6 million for the year ended December 31, 2013 due to the Company borrowing $6.0 million in March of 2013 and subsequently prepaying the loan in September of 2013 (see Write-off of Unamortized Loan Costs).

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 (the "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, we elected to prepay the Loan and paid Hercules approximately $6.4 million, including the $0.4 million fee discussed below, to settle all obligations to Hercules. Hercules agreed to waive the prepayment penalty of approximately $0.2 million.

Upon executing the loan documents on March 15, 2013 we became obligated to issue to the Lender a warrant to purchase shares of our common stock upon approval by our stockholders of a proposal to increase our number of authorized shares of common stock at our 2013 Annual Meeting of Stockholders. The number of shares that could be acquired upon exercise of the warrant and the exercise price per share, were not fixed on March 15, 2013 but would be determined when the warrant was issued based on a defined formula using trading prices of our common stock during certain periods prior to the issuance of the warrant. Our 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. The terms of the warrant were fixed on the date of issuance whereby the Lender received a warrant to purchase 693,202 shares of common stock at an exercise price of approximately $1.12 per share ("Warrant"). The Warrant expires on April 26, 2018.

For financial reporting purposes, the $6.0 million funded by the Lender on March 15, 2013 was allocated first to the fair value of our obligation to issue the warrant ("Warrant Obligation") that totaled approximately $0.6 million and the balance was reduced further by the Lender's costs and fees ("Costs"), resulting in an initial carrying value of the loan of approximately $5.3 million. 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 $.09 million 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 $1.16 to $1.18 per share, volatility of 77%, time to maturity of 5 years, exercise prices ranging from $1.15 to $1.16 and a risk free interest rate of return of .84%. Due to the nature of 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 $.7 million. The terms of the Loan required us to pay the Lender a fee of $.4 million at the maturity of the Loan (referred to as "Fee"). 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 was classified within stockholders equity.

As the result of us electing to prepay the loan on September 10, 2013, the unamortized loan discount, fee and deferred financing costs were expensed resulting in a loss on early extinguishment of debt of approximately $1.0 million.

Change in Fair Value of Warrant Liability

On October 29, 2013, we entered into a securities purchase agreement with certain accredited investors in connection with a registered offering of 4,228,181 shares of the Company's common stock, fully paid prefunded warrants ("Series B Warrants") to purchase up to 4,343,247 shares of its common stock and additional warrants ("Series A Warrants") to purchase up to 6,857,142 shares of its common stock for aggregate gross proceeds to the Company of $6.0 million. The Series A Warrants are exercisable beginning on May 1, 2014 at a price of $0.85 per share and expire on May 1, 2019. The Series B Warrants are exercisable immediately for no additional consideration. The offering closed on October 31, 2013.

The Series A Warrants have been recorded at fair value at the inception date of October 31, 2013, and at December 31, 2013, and will be recorded at their fair value at each subsequent balance sheet date. Any change in value between reporting periods is recorded as a non-operating, non-cash charge in the Statement of Operations. The change in fair value of the Series A warrant liability for the year ended December 31, 2013, was $.2 million.

The change in fair value of the Series A common stock warrants of $0.2 million combined with the change in fair value of the debt financing warrants provided for a total change in fair value of warrant liability at December 31, 2013 of approximately $0.3 million.

Other Income, net

In accordance with the terms of our DIFOTI sale and licensing agreement, KaVo will pay us an annual royalty based on the number of DIFOTI related systems sold per calendar year following their commercial re-launch. Other income for both of the years ended December 31, 2013 and 2012 is primarily the $.02 million royalty annual minimum.

Liquidity and Capital Resources

From inception, we have financed our operations primarily through the use of working capital from the sale of equity securities. As of December 31, 2013, we had $3.8 million in cash and cash equivalents as compared to $7.9 million at December 31, 2012. The $4.1 million decrease reflects $20.5 million of net cash provided by 2013 financing activities offset by $19.4 million of net cash used in operating activities and $5.2 million of net cash used in investing activities which was principally for the purchase of MelaFind® systems. Our cash and cash equivalents at December 31, 2013 are liquid investments in cash with two commercial banks and money market accounts held in accounts that substantially exceed FDIC limits.

In June 2012, the Company entered into a sales agreement with Cowen and Company, LLC, to sell shares of the Company's common stock through an "at-the-market" equity offering program (the "ATM Program"), which was terminated on February 15, 2013. During the year ended December 31, 2013, the Company sold approximately 4.7 million shares under the ATM Program for gross and net proceeds of approximately $8.8 million and $8.5 million, respectively. During the term of the ATM Program, the Company sold a total of approximately 6.6 million shares for aggregate gross and net proceeds of approximately $14.4 million and $13.8 million, respectively.

On February 12, 2013 the Company entered into an underwriting agreement with Cowen and Company, LLC, relating to the public offering of 6.1 million shares of the Company's common stock, at a price to the public of $1.30 per share less underwriting discounts and commissions. The gross proceeds to the Company from the sale of the Common Stock totaled $7.9 million. After deducting the underwriters' discounts and commissions and other estimated offering expenses payable by the Company, net proceeds were approximately $7.3 million. The Offering closed on February 15, 2013.

On March 15, 2013, the Company executed loan documents with Hercules Technology Growth Capital Inc., a venture capital lender, whereby the Company borrowed $6.0 million ("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 $6.4 million, including the end of term fee of $0.4 million, to settle all obligations to Hercules. Hercules agreed to waive the prepayment penalty of $0.2 million. In connection with the Loan, Hercules, as additional consideration, received a five year warrant to purchase 693,202 shares of common stock at an exercise price of approximately $1.12 per share. The prepayment of the Loan had no impact on the Warrants issued to Hercules.

On October 29, 2013, the Company entered into a securities purchase agreement with certain funds managed by Sabby Management, LLC in connection with a registered offering of 4,228,181 shares of the Company's common stock, fully paid prefunded warrants ("Series B Warrants") to purchase up to 4,343,247 shares of its common stock and additional warrants ("Series A Warrants") to purchase up to 6,857,142 shares of its common stock for aggregate gross proceeds to the Company of $6.0 million. The Series A Warrants are exercisable beginning on May 1, 2014 at a price of $0.85 per share and expire on May 1, 2019. The Series B Warrants are exercisable immediately for no additional consideration. The offering closed on October 31, 2013.

Subsequent to year end, on February 5, 2014, pursuant to a securities purchase agreement, dated as of January 31, 2014, with certain funds managed by Sabby Management, LLC (the Company's largest beneficial shareholder) and Broadfin Capital, LLC (together, the "Purchasers"), the Company sold (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 14,642,857 shares of common stock at an initial conversion price of $0.84, and (ii) warrants to purchase up to 13,297,297 shares of common stock for aggregate gross proceeds of $12.3 million. The warrants have an exercise price of $0.74 per share, are immediately exercisable and have a term of five years. The number of shares issuable upon conversion of the Series A Preferred Stock and exercise of the Warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar transactions. In connection with the financing, Broadfin Capital, LLC has been granted the right to designate one director to our Board of Directors, so as long as it retains 30% of its investment in the Series A Preferred Stock (or the shares of common stock underlying the Series A Preferred Stock) or holds any warrants, and the Purchasers have been granted rights of participation in future offerings of our securities for one year. As a condition of the financing, our directors, pursuant to subscription agreements dated as of January 31, 2014, purchased an aggregate of 202,703 shares of common stock, at a price of $0.74 per share, for aggregate gross proceeds of $.15 million. These securities were sold pursuant to an exemption under Section 4(a)(2) of the Securities Act of 1933 for transactions of an issuer not involving a public offering.

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. In addition to the registration rights, the Purchasers are entitled to receive liquidated damages upon the occurrence of a number 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 of the Company to file a resale registration statement by no later

than February 25, 2014 and the failure of the Company to have such resale registration statement declared effective by the Securities and Exchange Commission by no later than March 7, 2014. The liquated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquated damages payable is equal to 10% of the aggregate purchase price paid by each Purchaser for the first two events (and/or the monthly anniversary of an event), 7.5% of the aggregate purchase price paid by each Purchaser for the third event (and/or the monthly anniversary of an event), 2.5% of the aggregate purchase price paid by each Purchaser for the fourth event (and/or the monthly anniversary of an event), and 1% of the aggregate purchase price paid by each Purchaser for the next two events (and/or the monthly anniversary of an event), in all up to a total of 32% of the aggregate purchase price paid by each Purchaser. The liquidated damages are prorated on a daily basis for each event until such event is cured.

The terms of the Registration Rights Agreement required us to provide the Purchasers with a copy of the registration statement not less than 17 trading days prior to its filing with the SEC. Therefore, the Company was unable to file the initial re-sale registration statement by February 25, 2014 or become effective by March 7, 2014 and paid liquidated damages to the Purchasers in the aggregate amount of $2.5 million, and may be required to pay additional damages of $1.4 million.

Cash Flows from Operating Activities

Net cash used in operations was $19.4 million for the year ended December 31, 2013. For the year ended December 31, 2012, the net cash used in operations was $19.2 million. For both periods, cash used in operations was attributable primarily to net losses after adjustment for non-cash charges related to non-cash compensation, depreciation and other changes in operating assets and liabilities. Additionally in 2013, non-cash items were also attributable to a write-off of unamortized loan costs and impairment of long-lived assets.

Cash Flows from Investing Activities

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. For the year ended December 31, 2012 net cash used by investing activities was $6.2 million, and also principally related to the purchase of fixed assets.

Cash Flows from Financing Activities

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. For the year ended December 31, 2012, the net cash flows provided by financing activities was $5.2 million, which reflects the net proceeds received from our public offering of common stock and proceeds from the exercise of common stock options.

Operating Capital and Capital Expenditure Requirements

We face certain risks and uncertainties, which are present in many emerging medical device companies. At December 31, 2013, we had an accumulated deficit of $168.1 million. Our expenses will increase in connection with our continued commercialization and development activities related to MelaFind®. Having commenced commercialization in March 2012, we expect to incur additional medical, marketing and sales expenses in the near future and to incur additional contract manufacturing and inventory expenses in the future which will require additional funding. Furthermore, having recently commenced a refocused marketing strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma, we expect to incur additional expenses transitioning our operations and implementing our new refocused marketing strategy. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future and cannot determine at this time when we will generate any significant revenues.

Subsequent to year end, we raised approximately $11.5 million in net proceeds from a private offering of our convertible preferred stock, common stock warrants and common stock. In the first quarter of 2014, we paid a total of $2.5 million in liquidated damages to the investors in this private placement as a result of our failure to file and have declared effective a registration statement in accordance with the time periods set forth in a registration rights agreement between us and the investors. We believe, even with cash and cash equivalents held at December 31, 2013, and cash raised subsequent to year end, that there is significant doubt about our ability to continue as a going concern. We continue to assess the effects of our previously announced cost reduction plan and are prepared to reduce various operational costs. Should the Company experience unforeseen expenses, or if anticipated revenues are not realized, the effect could have a further negative impact on management’s estimated operating results over the next twelve months. If our existing cash is insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain a credit facility, which will be even more difficult due to current tightness in the credit markets. 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 would 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.

Because of the numerous risks and uncertainties associated with the development and commercialization of medical devices such as MelaFind® and operating our Company, we are unable to estimate the exact amounts of capital outlays and operating expenditures. 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 transitioning our operations and implementing a refocused 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 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 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.

Recently Adopted Accounting Pronouncements

The Financial Accounting Standards Board ("FASB") periodically issues new accounting standards in a continuing effort to improve standards of financial accounting and reporting. We have reviewed the recently issued pronouncements and concluded that there are no recently issued accounting pronouncements that we have yet to adopt, which we would expect to have a material effect on our financial position, results of operations or cash flows.

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, 2012 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, 2013. 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, 2012 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, 2013, 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. Our opinion is not modified with respect to this matter.

/s/ EisnerAmper LLP

New York, New York
March 17, 2014

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

	December 31, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,783	$ 7,862
Accounts receivable (net of allowance of $46 and $0 as of December 31, 2013 and 2012, respectively)	57	180
Inventory (net of reserve $325 and $0 as of December 31, 2013 and 2012, respectively) (See Note 4)	5,631	676
Prepaid expenses and other current assets	880	965
Total Current Assets	10,351	9,683
Property and equipment, net (See Note 5)	3,691	7,350
Patents and trademarks, net	42	47
Deferred financing costs	—	106
Other assets	48	84
Total Assets	**$ 14,132**	**$ 17,270**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable (includes related parties of $33 and $60 as of December 31, 2013 and 2012, respectively)	$ 1,479	$ 1,850
Accrued expenses (includes related parties of $48 and $0 as of December 31, 2013 and 2012, respectively)	844	956
Deferred placement revenue	244	172
Warrant liability (See Note 10)	3,017	—
Other current liabilities	68	41
Total Current Liabilities	5,652	3,019
Long Term Liabilities:		
Deferred placement revenue	64	132
Deferred rent	120	144
Total Long Term Liabilities	184	276
Total Liabilities	**5,836**	**3,295**
COMMITMENTS AND CONTINGENCIES		
Stockholders' Equity:		
Preferred stock—$0.10 par value; authorized 10,000,000 shares: issued and outstanding: none	—	—
Common stock—$0.001 par value; authorized 95,000,000 shares: Issued and outstanding 47,501,596 and 32,204,720 shares at December 31, 2013 and 2012, respectively.	48	32
Additional paid-in capital	176,396	156,143
Accumulated deficit	(168,148)	(142,200)
Total Stockholders' Equity	8,296	13,975
Total Liabilities and Stockholders' Equity	**$ 14,132**	**$ 17,270**

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, 2013	December 31, 2012
Net revenues	$ 536	$ 278
Cost of revenue	4,341	2,042
Gross profit	**(3,805)**	**(1,764)**
Operating expenses:		
Research and development	3,782	6,792
Selling, general and administrative	15,536	14,169
Impairment of long-lived assets	1,011	—
Total operating expenses	20,329	20,961
Operating loss	**(24,134)**	**(22,725)**
Other income (expenses):		
Interest income	8	32
Interest expense	(564)	—
Change in fair value of warrant liability	(296)	—
Write-off of unamortized loan costs	(983)	—
Other income, net	21	20
	(1,814)	52
Net loss	**$ (25,948)**	**$ (22,673)**
Basic and diluted net loss per common share	$ (0.60)	$ (0.74)
Basic and diluted weighted average number of common shares outstanding	42,894,500	30,762,610

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.
STATEMENT OF STOCKHOLDERS' EQUITY
Years ended December 31, 2012 and 2013
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2012	**30,308**	**$ 30**	**$ 149,304**	**$ (119,527)**	**$ 29,807**
Cashless exercise of options	12				—
Exercise of options	21		45		45
Issuance of shares of common stock in connection with Public Offering (net of issuance costs of $282)	1,864	2	5,306		5,308
Share-based compensation expense			1,488		1,488
Net loss				(22,673)	(22,673)
Balance at December 31, 2012	**32,205**	**32**	**156,143**	**(142,200)**	**13,975**
Issuance of shares of common stock in connection with Public Offering (net of issuance costs of $1,025)	10,814	11	15,714		15,725
Issuance of shares of common stock and warrants in connection with 2013 Direct Placement (net of issuance costs of $3,426)	4,228	4	2,569		2,573
Warrants issued in connection with loans payable			652		652
Exercise of options	18		18		18
Share-based compensation expense	237	1	1,300		1,301
Net loss				(25,948)	(25,948)
Balance at December 31, 2013	**47,502**	**$ 48**	**$ 176,396**	**$ (168,148)**	**$ 8,296**

The accompanying notes are an integral part of these financial statements

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

	December 31, 2013	December 31, 2012
Cash flows from operating activities:		
Net loss	$ (25,948)	$ (22,673)
Adjustments to reconcile net loss:		
Write-off of unamortized loan costs	983	—
Depreciation and amortization	2,439	970
Impairment of long-lived assets	1,011	—
Bad debt expense	46	—
Write-off of unamortized financing costs	41	62
Stock-based compensation	1,301	1,488
Amortization of deferred financing costs	250	—
Change in fair value of warrant liability	296	—
Inventory reserve	325	—
Changes in operating assets and liabilities:		
Accounts receivable	77	(180)
Inventory	121	(676)
Prepaid expenses and other current assets	86	96
Other assets	36	(20)
Accounts payable and accrued expenses	(484)	1,390
Other current liabilities	27	10
Deferred rent	(24)	6
Deferred revenue	4	303
Net cash used in operating activities	**(19,413)**	**(19,224)**
Cash flows from investing activities:		
Purchases of property and equipment	(5,188)	(6,158)
Net cash used in investing activities	**(5,188)**	**(6,158)**
Cash flows from financing activities:		
Net proceeds from private placements/public offerings	21,174	5,202
Net proceeds from long term debt	5,755	—
Repayment of long term debt	(6,425)	—
Proceeds from exercise of stock options	18	45
Net cash provided by financing activities	**20,522**	**5,247**
Net decrease in cash and cash equivalents	(4,079)	(20,135)
Cash and cash equivalents at beginning of period	**7,862**	**27,997**
Cash and cash equivalents at end of period	**$ 3,783**	**$ 7,862**
Supplemental Schedule of Noncash Investing and Financing Activities:		
Non-cash interest expense	$ —	$ 41
Reclassification of MelaFind® components from other assets to property and equipment	$ —	$ 522
Reclassification of warrant liability to stockholders equity	$ 652	$ —
Reclassification of MelaFind® components from property and equipment to 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. Company

MELA Sciences, Inc., a Delaware corporation (the "Company"), is a medical device company focused on the commercialization of our flagship product, MelaFind ® , the further design and development of MelaFind ® and our technology. MelaFind ® is a non-invasive, point-of-care (in the doctor's office) instrument to aid in the detection of melanoma. MelaFind ® 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 that were 'trained' on our proprietary database of melanomas and benign lesions. This then provides information to assist in the management of the patient's disease, including information useful in the decision of whether to biopsy the lesion.

The components of the MelaFind® system include:

- a *hand-held component*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- a *proprietary database* of pigmented skin lesions, believed to be the largest positive 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 written approval from the U.S. Food and Drug Administration ("FDA") for the MelaFind ® Pre-Market Approval ("PMA") application and in September 2011 received Conformite Europeenne ("CE") Mark approval for MelaFind ®. On March 7, 2012, the Company installed the first commercial MelaFind ® systems, and proceeded with the commercial launch of MelaFind ®. We are currently conducting a Post-Approval Study ("PAS") evaluating the sensitivity and false positive rate of physicians after using MelaFind®.

In 2012 the Company evolved from a research and development company to a commercial enterprise. The launch of MelaFind® in 2012, and the subsequent commercialization activities following the launch did not meet the Company's initial goals and objectives. Revenues were lower than forecasted and expenses continued to increase throughout 2012 and into 2013. Our cash used in operating activities for the year ended December 31, 2013 and December 31, 2012 totaled $19,413 and $19,224, respectively, and net revenues totaled $536 and $278, respectively.

In mid 2013, a significant cost reduction program was put into place (see Note 16). On November 11, 2013, a new CEO was brought on board and a newly refocused "Go-to-Market" strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma was adopted. As part of this strategy, in late December, we elected to change our business model from a rental to a sale model for the MelaFind® device. The Company has reduced its costs, brought new and experienced talent to its management team and has reconsidered the approach to the commercialization of the MelaFind® device. The Company has also begun the process of obtaining a coverage determination from the Centers for Medicare & Medicaid Services, the federal agency that administers Medicare, in order to obtain reimbursement by Medicare for use of the MelaFind® device. The Company anticipates that this process could take up to two years. Once a coverage determination has been made, the Company plans to seek reimbursement by Medicaid, Medicare and other third-party payers.

On August 22, 2013, the Company received a notice from The NASDAQ Stock Market that, for the previous 30 consecutive business days, the Company was not in compliance with a Nasdaq rule for continued listing that requires a listed company's common stock to maintain a minimum bid price of $1.00 per share. The Company was granted an automatic 180 grace period by NASDAQ in which to regain compliance. On February 19, 2014, we were notified by NASDAQ that the Company was eligible for an additional 180 day grace period and has until August 18, 2014 to regain compliance with NASDAQ's minimum bid price requirement.

On October 17, 2013, the FDA sent the Company a letter stating the information in the August 8, 2013 progress report with respect to the PAS was inadequate to allow the agency to complete its review and therefore the FDA asked for additional information. Because of rate of accrual issues, the FDA's letter informed the Company that its study status was revised on the FDA's website to "Progress Inadequate." On September 9, 2013, the Company placed this study on hold to investigate enrollment. On November 15, 2013, the Company responded to the FDA's letter, outlining an enrollment plan as well as a new enrollment schedule. On January 2, 2014, the FDA prompted an interactive review process to obtain further additional information regarding the Company's response. On January 13, 2014, the Company's enrollment plan and enrollment schedule was approved by the FDA and

the interactive review process was closed as the FDA deemed the Company has sufficiently met the reporting expectations of the report. The Company's new study timeline was approved for study restart in January 2014, steps to restart the study have been initiated. The FDA noted in their January 13, 2014 email that the status would remain as "Progress Inadequate" and that the status would be reassessed upon review of the next interim report date, February 8, 2014, based on the newly approved January 2014 restart timeline. As of the Company's February 24, 2014 teleconference with the FDA, they noted that they have not had time to read our February 8, 2014 report and therefore the status has not been reviewed.

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.

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. Management recently 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, as discussed below, in October 2013 the Company raised net proceeds of approximately $5,500 from the sale of common stock and warrants to strengthen the Company's financial position, and in February 2014 the Company raised net proceeds of approximately $11,500 from the sale of convertible preferred stock, common stock and warrants (see Note 17).

The Company continues to incur net losses. These net losses and the $6,400 payment to Hercules made in September 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, 2013, together with the net proceeds from the February 2014 financing and estimated revenue, there is significant doubt about our 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 reduce various operational costs. Although the Company has no specific arrangements or plans, the Company will need additional capital during the next 12 months, which may take the form of equity or debt, on either a loan or convertible basis. However, under the terms of the securities purchase agreement entered into in connection with its February 2014 financing, the Company is prohibited from issuing (or entering into any agreement to issue) any equity securities in connection with a financing until the later of July 31, 2014 or 2 months after the effectiveness of the re-sale registration statement the Company is required to file in connection with that financing.

The Company's financial statements are prepared using accounting principles generally accepted in the United States of America (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, 2013, the Company had an accumulated deficit of $168,148, had incurred a net loss for the year ended December 31, 2013 of $25,948 and had positive working capital of $4,699. Funding has been provided by related parties as well as new investors committed to make it possible to maintain, expand, and ensure the advancement of the MelaFind® product.

The Company expects expenses will increase in connection with its continued commercialization and development activities related to MelaFind®. Having commenced commercialization in March 2012, the Company expects to incur additional medical, marketing and sales expenses in the near future and to incur additional contract manufacturing and inventory expenses in the future which will require additional funding. Furthermore, having recently commenced a refocused marketing strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma, the Company expects to incur additional expenses continuing to transition its operations and implement its new refocused marketing strategy. As a result, the Company expects to continue to incur significant and increasing operating losses for the foreseeable future and cannot determine at this time when it will generate any significant revenues. As of December 31, 2013, the Company's total of cash and cash equivalents was approximately $3,783. Subsequent to year end, the Company raised approximately $12,300 in gross proceeds from a private placement of the Company's convertible preferred stock and warrants to purchase shares of its common stock. In the first quarter of 2014, the Company paid a total of $2,460, and may be required to pay an additional $1,476, in liquidated damages to the investors in this private placement as a result of its failure to file and have declared effective a registration statement in accordance with the time periods set forth in a registration rights agreement between the Company and the investors.

Should the Company experience unforeseen expenses, or if anticipated revenues are not realized, the effect could have a further negative impact on management's estimated operating results over the next twelve months. If existing cash is insufficient to satisfy the Company's liquidity requirements, or if it develops additional products, the Company may seek to sell additional equity or debt securities or obtain a credit facility, which will be even more difficult due to the current tightness in the credit markets. 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.

3. Summary of Significant Accounting Policies

Concentration of Credit Risk

The Company performs ongoing credit evaluations of its customers' financial condition and maintains an allowance for uncollectible accounts receivable based upon the expected collectability of all accounts receivable.

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 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 that are stated at the lower of cost (first-in, first-out) or market value. As of December 31, 2013 the reserve for obsolete inventory totaled $325. The Company reserved for specific inventory items that are no longer being used in the devices.

In mid 2013, a significant cost reduction program was put into place. On November 11, 2013, a new CEO was brought on board and a newly refocused "Go-to-Market" strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma was adopted. As part of this strategy, in late December, we elected to change our business model from a rental to a sale model for the MelaFind® device. In accordance with this new sales model, the Company has reclassed approximately $5,402 of MelaFind® devices from property and equipment into inventory.

Business Segments

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

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. While the Company was required to place the MelaFind ® systems with dermatologists for their exclusive use, under the Company's previous rental model with respect to MelaFind® placements, ownership of the MelaFind ® systems remains with the Company. In December 2013, the Company changed its business model from a rental and usage model, to a sales model for our MelaFind ® product. Therefore, the Company will recognize revenues for product sales when title and risk of loss transfers to customers, which is after installation and training on the MelaFind® system, and 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.

During 2013, the Company generated revenue from either usage based on the number of patient sessions, or lesions examined, or a fixed monthly fee. Electronic record cards activate the MelaFind ® system, capture data and store the data 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 we make 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 placement of the MelaFind® system in the doctor's office, the cost of consumables delivered at installation, the cost of the electronic record cards, technical support costs and depreciation expense of the MelaFind ® system placed with the customer which, under the Company's previous rental model with respect to MelaFind® placements, remains the property of the Company. 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, 2013 and 2012, the Company capitalized approximately $5,188 and $6,158, 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. Depreciation expense for the years ended December 31, 2013 and 2012 was $2,434 and $957, respectively.

Patents and Trademarks, Net

The Company capitalizes the costs of obtaining its patents and registration of Trademarks. Such costs are accumulated and capitalized during the filing periods, which can take several years to complete. Successful applications that result in the granting of a patent or trademark are then amortized over 15 years on a straight-line basis. Unsuccessful applications are written off and expensed in the fiscal period where the application is abandoned or discontinued.

Deferred Financing Costs

Financing costs incurred in connection with the Hercules Technology Growth Capital, Inc. ("Hercules") note payable were deferred and are being amortized over the term of the note using the effective interest rate method. These financing costs were written off when the loan was repaid in September 2013. As of December 31, 2013 and 2012 the Company recorded deferred financing costs of $0 and $106, respectively, in other assets in the accompanying balance sheets.

Deferred Revenue and Prepaid Expenses

Deferred placement revenue relates primarily to rental placement fees and product sales or services paid but not delivered at period end. The Company has certain customer arrangements providing for multiple years content services. To the extent deferred services are to be provided beyond twelve months they are treated as long-term. Prepaid expenses are recorded at amounts paid to suppliers or others. Amounts recorded are evaluated for impairment each reporting period.

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 exceeds 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. (See Note 5)

Research and Development

Expenditures for research and development are expensed as incurred.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service where we have 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, our estimates are most affected by our projections of the timing of services provided relative to the actual level of services provided by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. 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. We make these judgments based upon the facts and circumstances known to us and accrue for such costs in accordance with accounting principles generally accepted in the U.S. This is done as of each balance sheet date in our financial statements.

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.

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.

Stock-based compensation to non-employee consultants 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 which would favorably affect the effective tax rate if recognized in future periods, 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, 2013 and 2012 consist of stock options, warrants and restricted stock awards which are summarized as follows:

	Year Ended December 31,	
	2013	**2012**
Common stock options	3,065,714	2,426,533
Warrants	12,093,591	200,000
Restricted Stock Awards	99,375	—
Total	15,258,680	2,626,533

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 an asset had been impaired or 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 currently 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 6,857,142 common stock warrants issued in connection with the October 31, 2013 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 warrants issued by the Company in connection the transaction has been estimated using a Black-Scholes valuation.

Recently Issued Accounting Standards

The Financial Accounting Standards Board ("FASB") periodically issues new accounting standards in a continuing effort to improve standards of financial accounting and reporting. We have reviewed the recently issued pronouncements and concluded that there are no recently issued accounting pronouncements that the Company has yet to adopt that are expected to have a material effect on the Company's financial position, results of operations or cash flows.

Management's Evaluation of Subsequent Events

Management evaluates events that have occurred after the balance sheet date but before the financial statements are issued. Based upon the evaluation, management did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements (See Note 17).

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

Inventory consists of the following:

	December 31,	
	2013	**2012**
MelaFind® Systems	$ 5,402	$ —
Mela record cards	328	333
Accessories	226	343
	5,956	676
Reserve for obsolete inventory	(325)	—
	$ 5,631	$ 676

At December 31, 2013, under the Company's new sales model, approximately $5,402 of MelaFind ® systems have been reclassified from property and equipment into inventory.

5. Property and Equipment

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

	December 31,		**Estimated Useful Life**	**Useful Life**
	2013	**2012**		
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	2,023	2,023	3-5 years	3-5 years
MelaFind® Systems	5,081	6,306	3 years	3 years
	9,094	10,319		
Accumulated depreciation and amortization	(5,403)	(2,969)		
	$ 3,691	$ 7,350		

Depreciation expense amounted to approximately $2,434 and $957 for the years ended December 31, 2013 and 2012, respectively.

For the year ended December 31, 2013, the Company's marketing shifted focus to large cancer centers and high risk patients, and the Company took an impairment charge of approximately $1,011 against its MelaFind ® systems previously placed in locations that do not fit this profile. However, as these user agreements expire over the next 2 years, we anticipate that the affected systems will be redeployed in some capacity. Under the Company's new sales model, approximately $5,402 has been reclassified into inventory.

6. Patents and trademarks

Patents and trademarks as shown in the accompanying balance sheets are net of accumulated amortization of $232 and $227 at December 31, 2013 and 2012, respectively. Amortization expense related to all patents was approximately $5 and $12 for the years ended December 31, 2013 and 2012, respectively. Amortization expense of currently held patents is expected to amount to $5 for each of the years ending December 31, 2014 through 2018, 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:

2014	$ 478
2015	478
2016	477
TOTAL	$ 1,433

Rent expense charged to operations amounted to approximately $509 and $483 for the years ended December 31, 2013 and 2012, 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

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 and $151 for the years ended December 31, 2013 and 2012, respectively. On December 31, 2013 the Company ceased contributions and terminated the plan.

9. Debt

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 number of shares that could be acquired upon exercise of the warrant and the exercise price per share, were not fixed on March 15, 2013 but would be determined when the warrant was issued based on a defined formula using trading prices of the Company's common stock during certain periods prior to the issuance of the warrant. 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. The terms of the warrant were fixed on the date of issuance whereby the Lender received a warrant to purchase 693,202 shares of common stock at an exercise price of approximately $1.12 per share ("Warrant"). The Warrant expires 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 of our obligation to issue the warrant ("Warrant Obligation") that totaled approximately $563 and the balance was reduced further by the Lender's costs and fees ("Costs"), 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 $1.16 to $1.18 per share, volatility of 77%, time to maturity of 5 years, exercise prices ranging from $1.15 to $1.16 and a risk free interest rate of return of .84%. Due to the nature of 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 required us to pay the Lender a fee of $425 at the maturity of the Loan (referred to as "Fee"). 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 was classified within stockholders equity.

As the result of us electing to prepay the loan on September 10, 2013, the unamortized loan discount, fee and deferred financing costs that were expensed were 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 payable, and derivative warrant liabilities. The recorded values of cash equivalents 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, 2013 and October 31, 2013 is as follows:

Black-Scholes Warrant Pricing	**October 31, 2013**	**December 31, 2013**
Stock Price	$ 0.85	$ 0.85
Risk-free Rate (5-year U.S. Treasury Yield)	1.31%	1.75%
Volatility (Annual)	94.78%	93.43%
Time to Maturity (Years)	5.50	5.33

At December 31, 2013 and December 31, 2012, the estimated fair values of the liabilities measured on a recurring basis are as follows:

	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

	Fair Value Measurements at December 31, 2012			
	Balance at December 31, 2012	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant derivative liabilities	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —

The following tables present the activity for liabilities measured at estimated fair value using unobservable inputs for the years ended December 31, 2013 and 2012:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
	Warrant Derivative Liabilities
Beginning Balance at January 1, 2013	$ —
Issuance of warrants with 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

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. 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. As of December 31, 2013, there are no shares of preferred stock issued or outstanding.

On February 5, 2014, pursuant to a securities purchase agreement, dated as of January 31, 2014, with certain funds managed by Sabby Management, LLC and Broadfin Capital, LLC (together, the "Purchasers"), the Company sold (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 14,642,857 shares of common stock at an initial conversion price of $0.84, and (ii) warrants to purchase up to 13,297,297 shares of common stock for aggregate gross proceeds of $12,300. The warrants have an exercise price of $0.74 per share, are immediately exercisable and have a term of five years. The number of shares issuable upon conversion of the Series A Preferred Stock and exercise of the Warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar transactions. In connection with the financing, Broadfin Capital, LLC has been granted the right to designate one director to our Board of Directors, so as long as it retains 30% of its investment in the Series A Preferred Stock (or the shares of common stock underlying the Series A Preferred Stock) or holds any warrants, and the Purchasers have been granted rights of participation in future offerings of

our securities for one year. As a condition of the financing, our directors, pursuant to subscription agreements dated as of January 31, 2014, purchased an aggregate of 202,703 shares of common stock, at a price of $0.74 per share, for aggregate gross proceeds of $150,000 (See Note 17).

Common Stock

The Company is authorized to issue 95,000,000 shares of Common Stock with a par value of $0.001 per share.

In June 2012, the Company entered into a sales agreement with Cowen and Company, LLC, to sell shares of the Company's common stock through an "at-the-market" equity offering program (the "ATM Program"), which was terminated on February 15, 2013. During the year ended December 31, 2013, the Company sold approximately 4.7 million shares under the ATM Program for gross and net proceeds of approximately $8,800 and $8,500, respectively. During the term of the ATM Program, the Company sold a total of approximately 6.6 million shares for aggregate gross and net proceeds of approximately $14,400 and $13,800, respectively.

On February 12, 2013 the Company entered into an underwriting agreement with Cowen and Company, LLC, relating to the public offering of 6.1 million shares of the Company's common stock, at a price to the public of $1.30 per share less underwriting discounts and commissions. The gross proceeds to the Company from the sale of the Common Stock totaled $7,900. After deducting the Underwriters' discounts and commissions and other estimated offering expenses payable by the Company, net proceeds were approximately $7,300. The offering closed on February 15, 2013. The Common Stock was offered and sold pursuant to the Company's Prospectus dated June 1, 2010 and the Company's Prospectus Supplement filed with the Securities and Exchange Commission (the "SEC") on February 11, 2013, in connection with a takedown from the Company's effective shelf registration statement on Form S-3 (File No. 333-167113) declared effective by the SEC on June 1, 2010.

Warrants

On March 15, 2013, the Company executed loan documents with Hercules Technology Growth Capital Inc. In connection with the Loan, Hercules, as additional consideration, received a five year warrant to purchase 693,202 shares of common stock at an exercise price of approximately $1.12 per share.

October 29, 2013, the Company entered into a securities purchase agreement with certain accredited investors in connection with a $6,000 registered offering of 4,228,181 shares of the Company's common stock, fully paid prefunded warrants ("Series B Warrants") to purchase up to 4,343,247 shares of its common stock and additional warrants ("Series A Warrants") to purchase up to 6,857,142 shares of its common stock. The Series A Warrants are exercisable beginning on May 1, 2014 at a price of $0.85 per share and expire on May 1, 2019. The Series B Warrants are exercisable immediately for no additional consideration. The offering closed on October 31, 2013.

The Series A Warrants have non-standard terms as they relate to a fundamental transaction and require a net-cash settlement upon a change in control of the Company and therefore are classified as a derivative. Therefore, these warrants have been recorded at fair value at the inception date of October 31, 2013, and will be recorded at their respective fair values at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge in the Statements of Operations. The change in fair value of the warrant liability for the year ended December 31, 2013, was $296, which includes a change in fair value from the Series A warrants of $205.

As of December 31, 2013, the Company had the following warrants issued:

Issue Date	Holder	Total Warrants	Ex. Price
5/7/2009	Kingsbridge Capital Limited	200,000	$ 11.35
4/26/2013	Hercules Technology Growth Capital	693,202	$ 1.12
10/31/2013	Sabby Management, LLC "Series A"	6,857,142	$ 0.85
10/31/2013	Sabby Management, LLC "Series B Prefunded Warrants"	4,343,247	$ 0.70
		12,093,591	

12. Stock-Based Compensation

Stock Options

On April 25, 2013, at the Company's 2013 Annual Meeting of Stockholders, the Company's stockholders approved the Company's adoption of the new 2013 Stock Incentive Plan ("2013 Plan") having terms substantially similar to the Company's 2005 Stock Incentive Plan (the "2005 Plan") and having 3,500 shares available for issuance in respect of awards made there under. As of December 31, 2013, the aggregate number of shares of common stock remaining available for issuance for awards under the 2013 Plan and the 2005 Plan totaled approximately 3,729,853.

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 Plan are generally time-based or performance-based options and vesting varies accordingly. Options under the plans expire up to a maximum of ten years from the date of grant. The plans provide for the granting of a maximum number of shares of common stock of 7,224,028 of which 3,729,853 are available for future grant as of December 31, 2013. Compensation expense recognized in the Statement of Operations during 2013 and 2012 for stock options and restricted stock awards amounted to $1,301 and $1,488, respectively. Cash received from options exercised under all share-based payment arrangements for the years ended December 31, 2013 and 2012 was $18 and $45, respectively.

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, 2013	December 31, 2012
Expected life	5-10 years	5-10 years
Expected volatility	72-77%	74-80%
Risk-free interest rate	0.71-2.45%	0.91-1.60%
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 interest rate is based on rates provided by the U.S. Treasury with a term equal to the expected life of the option. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

At December 31, 2013, stock options to purchase 3,065,714 shares of common stock at exercise prices ranging from $0.65 to $10.35 per share are outstanding and are exercisable at various dates through 2023. The total number of options exercisable at December 31, 2013 and 2012 was 1,261,355 and 1,620,320 respectively, with weighted average exercise prices of $2.56 and $3.99, respectively. The aggregate intrinsic value of the options exercisable at December 31, 2013 is $0.

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 Insintric Value
Outstanding at December 31, 2011	2,057,104	4.35	6.6	
Granted	863,202	3.35	9.5	
Exercised	(61,796)	2.91		
Forfeited or expired	(431,977)	4.44		
Outstanding at December 31, 2012	2,426,533	4.01	7.0	$ 29
Granted	4,994,465	1.46	9.5	
Exercised	(18,059)	1.00		17
Forfeited or expired	(4,337,225)	2.77		27
Outstanding at December 31, 2013	3,065,714	1.62	9.0	
Vested and exercisable at December 31, 2013	1,261,355	$ 2.56	8.1	$ —

During the years ended December 31, 2013 and 2012 the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was $0.60 and $2.28 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2013 and 2012 was $17 and $86, respectively. The requisite service periods for options granted during 2013 and 2012 for employees was four years and for directors was one year.

The following table summarizes information about stock options outstanding at December 31, 2013:

	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
$0.65-$3.00	2,412,651	9.65 years	$ 0.89	694,742	$ 1.17
$3.01-$6.00	500,513	7.72 years	3.40	441,038	3.38
$6.01-$10.35	152,550	3.35 years	7.28	125,575	7.38
$0.65-$10.35	3,065,714	9.02 years	$ 1.62	1,261,355	$ 2.56

As of December 31, 2013, of the total 3,065,714 options outstanding, 1,804,359 have not vested. Of this total unvested amount, 650,850 will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. There was $755 of total unrecognized compensation cost related to unvested options, of which approximately $308 will be recognized upon achievement of performance milestones and $447 upon completion of the requisite service period. On February 11, 2013, the Company's former chief executive officer contractually agreed to not exercise 900,000 fully vested options until such time as the stockholders of the Company approve 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 900,000 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.

13. 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 $20 in royalty income in each of the years in the two year period ended December 31, 2013.

14. Related Party Agreements

Consulting Agreement with Gerald Wagner, Ph.D.

In January 2007, Dr. Wagner, a former Director on the Company's Board of Directors, entered into an amended and restated consulting contract with the Company. Under the terms of the amended contract, Dr. Wagner was paid a monthly retainer of $2.5 and was paid $2.5 for each additional consulting day. This amended agreement ended at the option of Dr. Wagner or the Company at any time, by providing fifteen days prior written notice, or immediately upon the mutual agreement of the Company and Dr. Wagner. The amounts paid to Dr. Wagner amounted to $0 and $30 in 2013 and 2012. Dr. Wagner resigned from the Company's Board of Directors in December 2011 with the consulting contract remaining in effect until termination on December 31, 2012.

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.

15. 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, 2013 and 2012.

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,	
	2013	2012
Computed expected tax benefit	$ (8,822)	$ (7,709)
State tax benefit, net of federal effect	(1,557)	(1,360)
Increase in the valuation allowance	10,379	9,069
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, 2013 and 2012 are as follows:

	December 31,	
	2013	2012
Deferred tax assets:		
Net operating loss carryforward	$ 35,086	$ 26,471
Capitalized research and developmental costs	27,794	26,511
Non-cash compensation	3,681	3,200
Total deferred tax assets	66,561	56,182
Less valuation allowance	(66,561)	(56,182)
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, 2012 and 2013. The Company's valuation allowance against its deferred tax assets increased by $10,379 and $9,069 for the years ended December 31, 2013 and 2012, respectively.

At December 31, 2013, the Company has net operating loss carryforwards of approximately $87,000 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 Company believes that these limitations may impact the Company's ability to utilize its net operating losses in the future. The February 2014 equity raise 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 which would favorably affect the effective tax rate if recognized in future periods, 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.

16. Restructuring Charge

As discussed in Note 1, in response to recurring operating losses and limited liquidity, during August 2013 the Company's Board of Directors approved the Cost Reduction Plan that included a reduction in work force and 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 that is reflected in the statement of operations as increases in cost of revenue, research and development and selling, general and administrative expenses of approximately $100, for the year ended December 31, 2013. As of December 31, 2013 substantially all termination benefits have been paid.

17. Subsequent Events

On February 5, 2014, pursuant to a securities purchase agreement, dated as of January 31, 2014, with certain funds managed by Sabby Management, LLC. and Broadfin Capital, LLC (together, the "Purchasers"), the Company sold (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 14,642,857 shares of common stock at an initial conversion price of $0.84, and (ii) warrants to purchase up to 13,297,297 shares of common stock for aggregate gross proceeds of $12,300. The warrants have an exercise price of $0.74 per share, are immediately exercisable and have a term of five years. The number of shares issuable upon conversion of the Series A Preferred Stock and exercise of the Warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar transactions. In connection with the financing, Broadfin Capital, LLC has been granted the right to designate one director to our Board of Directors, so as long as it retains 30% of its investment in the Series A Preferred Stock (or the shares of common stock underlying the Series A Preferred Stock) or holds any warrants, and the Purchasers have been granted rights of participation in future offerings of our securities for one year. As a condition of the financing, our directors, pursuant to subscription agreements dated as of January 31, 2014, purchased an aggregate of 202,703 shares of common stock, at a price of $0.74 per share, for aggregate gross proceeds of $150,000.

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. In addition to the registration rights, the Purchasers are entitled to receive liquidated damages upon the occurrence of a number 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 of the Company to file a resale registration statement by no later than February 25, 2014 and the failure of the Company to have such resale registration statement declared effective by the Securities and Exchange Commission (the "SEC") by no later than March 7, 2014. The liquated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquated damages payable is equal to 10% of the aggregate purchase price paid by each Purchaser for the first two events (and/or the monthly anniversary of an event), 7.5% of the aggregate purchase price paid by each Purchaser for the third event (and/or the monthly anniversary of an event), 2.5% of the aggregate purchase price paid by each Purchaser for the fourth event (and/or the monthly anniversary of an event), and 1% of the aggregate purchase price paid by each Purchaser for the next two events (and/or the monthly anniversary of an event), in all up to a total of 32% of the aggregate purchase price paid by each Purchaser. The liquidated damages are prorated on a daily basis for each event until such event is cured.

The terms of the Registration Rights Agreement required us to provide the Purchasers with a copy of the registration statement not less than 17 trading days prior to its filing with the SEC. The Company was unable to file the initial re-sale registration statement by February 25, 2014 or have it declared effective by March 7, 2014 and paid liquidated damages to the Purchasers in the aggregate amount of $2,460.

On February 19, 2014, the Company was notified by NASDAQ that the Company was eligible for an additional 180 day grace period and has until August 18, 2014 to regain compliance with NASDAQ's minimum bid price requirement.

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

Our Company's chief executive officer and acting chief financial officer, as well as our Controller have evaluated the effectiveness of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities and Exchange Act of 1934) as of December 31, 2013.

Based on such evaluation, our chief executive officer and acting chief financial officer, as well as Controller have concluded that, as of December 31, 2013, our disclosure controls and procedures were effective to ensure that the information we are required to disclose in reports that we file or submit to the SEC is (1) recorded, processed, summarized and reported within the time periods specified under the rules and forms of the SEC and (2) accumulated and communicated to our management, including our chief executive officer and acting chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

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, 2013 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.

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.* Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2013.

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

Not applicable.

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 Securities and Exchange Commission in connection with the 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, 2013, 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).
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).
10.1*#	Form of Indemnification Agreement for directors and executive officers.
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 January 5, 2004 between the Registrant and Joseph V. Gulfo (Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), filed on June 3, 2005).
10.4*	Amended and Restated Consulting Agreement effective as of April 1, 2006 between the Registrant and Gerald Wagner Consulting LLC. (Incorporated by reference to the Registrant's Annual Report on Form 10-K filed on March 29, 2006).
10.5*	Employment Offer Letter, dated April 24, 2006, between the Registrant and Richard I. Steinhart. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 27, 2006).
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*	Amendment No. 1 to Amended and Restated Consulting Agreement dated as of January 30, 2007 by and among the Registrant, Gerald Wagner and Gerald Wagner Consulting LLC. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 31, 2007).
10.8	Common Stock Purchase Agreement dated as of May 27 between Electro-Optical Sciences, Inc. and Kingsbridge Capital Limited. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on May 8, 2009).
10.9	Registration Rights Agreement dated as of May 7, 2009 between Electro-Optical Sciences, Inc. and Kingsbridge Capital Limited.(Incorporated by reference to the Registrant's Current Report on Form 8-K filed on May 8, 2009).
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).

Exhibit Number	Exhibit Title
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	Sales Agreement dated June 15, 2012 between MELA Sciences, Inc. and Cowen and Company, LLC (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on June 15, 2012)
10.15	Underwriting Agreement, dated February 12, 2013, by and between MELA Sciences, Inc. and Cowen and Company, LLC (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 12, 2013)
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*	Employment Agreement, dated June 21, 2013, between Robert C. Coradini and MELA Sciences, Inc. (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).
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*	Employment Agreement, dated as of November 6, 2013, by and between MELA Sciences, Inc. and Rose Crane (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 12, 2013).
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#	Letter regarding Director Designation Right, dated February 5, 2014, from MELA Sciences, Inc. to Broadfin Healthcare Master Fund, LTD.
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, 2012 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/ Rose Crane
Rose Crane
President and Chief Executive Officer
(Principal Executive Officer)

Dated: March 17, 2014

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/ Rose Crane **Rose Crane**	President and Chief Executive Officer (Principal Executive Officer)	March 17, 2014
/s/ Mary Phelan **Mary Phelan**	Controller (Principal Financial and Accounting Officer)	March 17, 2014
/s/ Robert Coradini **Robert Coradini**	Director	March 17, 2014
/s/ Anthony Dimun **Anthony Dimun**	Director	March 17, 2014
/s/ Kathryn Swintek **Kathryn Swintek**	Director	March 17, 2014
/s/ Jeffrey O'Donnell **Jeffrey O'Donnell**	Director	March 17, 2014
/s/ David K. Stone **David K. Stone**	Director	March 17, 2014
/s/ LuAnn Via **LuAnn Via**	Director	March 17, 2014

Exhibit 10.1

MELA SCIENCES, INC.

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("Agreement") is effective as of [ ], by and between MELA Sciences, Inc., a Delaware corporation (the "Company"), and [ ] ("Indemnitee").

RECITALS

A. The Company recognizes that competent and experienced persons are increasingly reluctant to serve or to continue to serve as directors and officers of corporations unless they are protected by comprehensive liability insurance or indemnification, or both, due to the increased exposure to litigation costs and risks resulting from their service to such corporations, and due to the fact that the exposure to or risks of shareholder claims or litigation frequently bears no reasonable relationship to the compensation of such directors and officers;

B. The statutes and judicial decisions regarding the duties of directors and officers are often difficult to apply, ambiguous, or conflicting, and therefore fail to provide such directors and officers with adequate, reliable information as to the legal risks to which they are exposed or regarding the proper course of action to take;

C. The Company and Indemnitee recognize that plaintiffs often seek damages in such large amounts and the costs of litigation may be so enormous (whether or not the case is meritorious), that the defense and/or settlement of such litigation is often beyond the personal financial resources of individual directors and officers;

D. The Company believes that it is unfair for its directors and officers to assume the risk of huge judgments and other expenses which may occur in cases in which the director and officer received no personal profit and in cases where the director or officer was not culpable;

E. The Company, after reasonable investigation, has determined that the liability insurance coverage presently available to the Company may be inadequate in certain circumstances to cover all possible claims for which Indemnitee would be protected. The Company believes that the interests of the Company and its stockholders would be best served by a combination of such insurance and the indemnification by the Company of the directors and officers of the Company;

F. The Company's Certificate of Incorporation and Bylaws require the Company to indemnify its directors and officers to the fullest extent permitted by the Delaware General Corporation Law (the "DGCL"). The Bylaws expressly provide that the indemnification provisions set forth therein are not exclusive, and contemplate that contracts may be entered into between the Company and its directors and officers with respect to indemnification;

G. Section 145 of DGCL ("Section 145"), under which the Company is organized, empowers the Company to indemnify its officers, directors, employees and agents by agreement and to indemnify persons who serve, at the request of the Company, as the directors, officers, employees or agents of other corporations or enterprises, and expressly provides that the indemnification provided by Section 145 is not exclusive;

H. Section 102(b)(7) of the DGCL allows a corporation to include in its certificate of incorporation a provision limiting or eliminating the personal liability of a director for monetary damages in respect of claims by shareholders or corporations for breach of certain fiduciary duties, and the Company has so provided in its Certificate of Incorporation that each director shall be exculpated from such liability to the maximum extent permitted by law;

I. The Board of Directors of the Company has determined that contractual indemnification as set forth herein is not only reasonable and prudent but also promotes the best interests of the Company and its stockholders;

J. The Company desires and has requested Indemnitee to serve or continue to serve as a director or officer of the Company free from undue concern for unwarranted claims for damages arising out of or related to such services to the Company; and

K. Indemnitee is willing to serve, continue to serve or to provide additional service for or on behalf of the Company on the condition that Indemnitee is furnished the indemnity provided herein.

NOW, THEREFORE, the Company and Indemnitee hereby agree as set forth below.

1. Certain Definitions.

a. "Change in Control" shall mean, and shall be deemed to have occurred if, on or after the date of this Agreement, (i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended), other than a trustee or other fiduciary holding securities under an employee benefit plan of the Company acting in such capacity or a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing more than 50% of the total voting power represented by the Company's then outstanding Voting Securities, (ii) during any period of 24 consecutive, full-calendar months, individuals who at the beginning of such period constitute the Board of Directors of the Company and any new director whose election by the Board of Directors or nomination for election by the Company's stockholders was approved by a vote of at least two thirds (2/3) of the directors then still in office who either were directors at the beginning of such 24-month period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof, (iii) the stockholders of the Company approve a merger or consolidation of the Company with any other corporation other than a merger or consolidation which would result in the Voting Securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into Voting Securities of the surviving entity) at least 51% of the total voting power represented by the Voting Securities of the Company or such surviving entity outstanding immediately after such merger or consolidation, or (iv) the stockholders of the Company approve a plan of complete liquidation of the Company or an agreement for the sale or disposition by the Company (in one transaction or a series of related transactions) of all or substantially all of the Company's assets.

b. "Claim" shall mean with respect to a Covered Event, any threatened, pending or completed action, suit, proceeding or alternative dispute resolution mechanism, or any hearing, inquiry or investigation that Indemnitee in good faith believes might lead to the institution of any such action, suit, proceeding or alternative dispute resolution mechanism, whether civil, criminal, administrative, investigative or other.

c. "Covered Event" shall mean any event or occurrence related to the fact that Indemnitee is or was a director, officer, employee, agent or fiduciary of the Company, or any Subsidiary of the Company, or is or was serving at the request of the Company as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action or inaction on the part of Indemnitee while serving in such capacity.

d. "Expenses" shall mean any and all expenses (including attorneys' fees and all other costs, expenses and obligations incurred in connection with investigating, defending, being a witness in or participating in (including on appeal), or preparing to defend, to be a witness in or to participate in, any action, suit, proceeding, alternative dispute resolution mechanism, hearing, inquiry or investigation), judgments, fines, penalties and amounts paid in settlement (if such settlement is approved in advance by the Company, which approval shall not be unreasonably withheld) of any Claim and any federal, state, local or foreign taxes imposed on the Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement.

e. "Expense Advance" shall mean a payment of Expenses to Indemnitee pursuant to Section 3 in advance of the settlement of or final judgment in any action, suit, proceeding or alternative dispute resolution mechanism, hearing, inquiry or investigation that constitutes a Claim.

f. "Independent Legal Counsel" shall mean an attorney or firm of attorneys, selected in accordance with the provisions of Section 2(d) hereof, who shall not have otherwise performed services for the Company or one or more indemnitees (including Indemnitee) within the last two years (other than acting as an Independent Legal Counsel in accordance with the terms of this Agreement).

g. References to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on Indemnitee with respect to an employee benefit plan; and references to "serving at the request of the Company" shall include any service as a director, officer, employee, agent or fiduciary of the Company which imposes duties on, or involves services by, such director, officer, employee, agent or fiduciary with respect to an employee benefit plan, its participants or its beneficiaries; and if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan, Indemnitee shall be deemed to have acted in a manner "not opposed to the best interests of the Company" as referred to in this Agreement.

h. "Reviewing Party" shall mean, subject to the provisions of Section 2(d), any person or body appointed by the Board of Directors in accordance with applicable law to review the Company's obligations hereunder and under applicable law, which may include (i) a majority of the directors who are not parties to such action, suit or proceeding, even though less than a

quorum or (ii) a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or if such directors so direct, by Independent Legal Counsel designated in writing by such directors or the Board of Directors.

i. "Section" refers to a section of this Agreement unless otherwise indicated.

j. "Subsidiary" shall mean a corporation or other entity (i) 50% or more of whose outstanding shares or securities (representing the right to vote for the election of directors or other managing authority) are, or (ii) which does not have outstanding shares or securities (as may be the case in a partnership, joint venture or unincorporated association), but 50% or more of whose ownership interest representing the right to make decisions for such other entity is, now or hereafter, owned or controlled, directly or indirectly, by the Company, or one or more Subsidiaries.

k. "Voting Securities" shall mean any securities of the Company that vote generally in the election of directors.

2. Indemnification.

a. Indemnification of Expenses. Subject to the provisions of Section 2(b) below, the Company shall indemnify Indemnitee for Expenses to the fullest extent permitted by law if Indemnitee was or is or becomes a party to or witness or other participant with respect to, or is threatened to be made a party to or witness or other participant with respect to, any Claim, including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses.

b. Review of Indemnification Obligations. Notwithstanding the foregoing, in the event any Reviewing Party shall have determined, in good faith (and in a written opinion, in any case in which Independent Legal Counsel is the Reviewing Party), that Indemnitee is not entitled to be indemnified hereunder, whether pursuant to Section 11 or otherwise, (i) the Company shall have no further obligation under Section 2(a) to make any payments to Indemnitee not made prior to such determination by such Reviewing Party, and (ii) the Company shall be entitled to be reimbursed by Indemnitee (who hereby agrees to reimburse the Company) for all Expenses theretofore paid to Indemnitee to which Indemnitee is not entitled hereunder; provided, however, that if the Reviewing Party's determination is based on Section 11(a) hereof and Indemnitee has commenced or thereafter commences a legal proceeding or proceedings in a court of competent jurisdiction to secure a determination that Indemnitee is entitled to be indemnified hereunder under applicable law, any determination made by any Reviewing Party that Indemnitee is not entitled to be indemnified shall not be binding and Indemnitee shall not be required to reimburse the Company for any Expenses theretofore paid in indemnifying Indemnitee until a final judicial determination is made with respect thereto (as to which all rights of appeal therefrom have been exhausted or lapsed). Indemnitee's obligation to reimburse the Company for any Expenses shall be unsecured and no interest shall be charged thereon unless and until a final judicial determination is made (as to which all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee is required to reimburse the Company, after which the Company may charge interest from the date of such determination at such rates as are permitted by applicable law.

c. Indemnitee Rights on Unfavorable Determination; Binding Effect. If any Reviewing Party determines that Indemnitee substantively is not entitled to be indemnified hereunder in whole or in part, Indemnitee shall have the right to commence litigation seeking an initial determination by the court challenging any such determination by such Reviewing Party or any aspect thereof, including the legal or factual bases therefor, and, subject to the provisions of Section 17, the Company hereby consents to service of process and to appear in any such proceeding and to use its reasonable efforts to cause the Reviewing Party to cooperate with respect to such proceeding. Absent such litigation, any determination by any Reviewing Party shall be conclusive and binding on the Company and Indemnitee.

d. Selection of Reviewing Party; Change in Control. If there has not been a Change in Control (or, there has been a Change in Control which has been approved by a majority of the Company's Board of Directors who were directors immediately prior to such Change in Control), any Reviewing Party shall be selected by the Board of Directors. If there has been a Change in Control (other than a Change in Control which has been approved by a majority of the Company's Board of Directors who were directors immediately prior to such Change in Control), any Reviewing Party with respect to all matters thereafter arising concerning the rights of Indemnitee to indemnification of Expenses under this Agreement or any other agreement or under the Company's Certificate of Incorporation (or articles of incorporation in the case of a Subsidiary incorporated in a state other than Delaware) or Bylaws as now or hereafter in effect, or under any other applicable law, if desired by Indemnitee, shall be Independent Legal Counsel selected by the Board of Directors and approved by Indemnitee (which approval shall not be unreasonably withheld or delayed). Such counsel, among other things, shall render its written opinion to the Company and Indemnitee as to whether and to what extent Indemnitee would be entitled to be indemnified hereunder under applicable law, and the Company agrees to abide by such opinion. The Company agrees to pay the reasonable fees of the Independent Legal Counsel referred to above. Notwithstanding any other provision of this Agreement, the Company shall not be required to pay for more than one Independent Legal Counsel in

connection with all matters concerning the Indemnitee, and such Independent Legal Counsel shall be the Independent Legal Counsel for any or all other indemnitees unless (i) the employment of separate counsel by one or more Indemnitees has been previously authorized by the Company in writing, or (ii) the Indemnitee shall have provided to the Company a written statement that such Indemnitee has reasonably concluded that there may be a conflict of interest between such Indemnitee and the other indemnitees with respect to the matters arising under this Agreement.

e. Mandatory Payment of Expenses. Notwithstanding any other provision of this Agreement other than Section 6 and 11 hereof, to the extent that Indemnitee has been successful on the merits or otherwise, including, without limitation, the dismissal of an action without prejudice, in defense of any Claim, Indemnitee shall be indemnified against all Expenses incurred by Indemnitee in connection therewith.

3. Expense Advances.

a. Undertaking; Obligation to Make Expense Advances. Execution and delivery to the Company of this Agreement by Indemnitee shall constitute an undertaking by the Indemnitee to repay any amounts paid, advanced or reimbursed by the Company pursuant to this Agreement in respect of Expenses relating to, arising out of or resulting from any Claim as to which it shall be determined, as described in Section 2(b), following final disposition of such Claim, that the Indemnitee is not entitled to indemnification hereunder. Upon such execution and delivery of this Agreement by the Indemnitee, and execution and delivery by the Company, the Company shall make Expense Advances to Indemnitee.

b. Form of Undertaking. Any obligation to repay any Expense Advances hereunder pursuant to the written undertaking by the Indemnitee contained herein shall be unsecured, and no interest shall be charged thereon, unless and until a court having jurisdiction in such matter has finally judicially determined (as to which determination all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee is so obligated, after which the Company may charge interest from the date of such determination at such rates as are permitted by applicable law.

4. Procedures for Indemnification and Expense Advances.

a. Timing of Payments. All payments of Expenses (including without limitation Expense Advances) by the Company to the Indemnitee pursuant to this Agreement shall be made to the fullest extent permitted by law as soon as practicable after written demand by Indemnitee therefor is presented to the Company, but in no event later than thirty (30) business days after such written demand by Indemnitee is presented to the Company, except in the case of Expense Advances, which shall be made no later than ten (10) business days after such written demand by Indemnitee is presented to the Company.

b. Notice/Cooperation by Indemnitee. Indemnitee shall, as a condition precedent to Indemnitee's right to be indemnified or Indemnitee's right to receive Expense Advances under this Agreement, give the Company notice in writing as soon as practicable of any Claim made against Indemnitee for which indemnification will or could be sought under this Agreement. Notice to the Company shall be directed to the Chief Executive Officer of the Company at the address shown on the signature page of this Agreement (or such other address as the Company shall designate in writing to Indemnitee). In addition, Indemnitee shall give the Company such information and cooperation as the Company may reasonably require and as shall be within Indemnitee's power. Indemnitee shall also not make any admission or enter into or otherwise agree to any settlement with respect to any Claim without the consent of the Company (which consent shall not be unreasonably withheld, conditioned or delayed).

c. No Presumptions; Burden of Proof. For purposes of this Agreement, the termination of any Claim by judgment, order, settlement (whether with or without court approval) or upon a plea of nolo contendere or its equivalent, shall not create a presumption that Indemnitee did not meet any particular standard of conduct or have any particular belief or that a court has determined that indemnification is not permitted by this Agreement or applicable law. In addition, neither the failure of any Reviewing Party to have made a determination as to whether Indemnitee has met any particular standard of conduct or had any particular belief, nor an actual determination by any Reviewing Party that Indemnitee has not met such standard of conduct or did not have such belief, prior to the commencement of legal proceedings by Indemnitee to secure a judicial determination that Indemnitee should be indemnified under this Agreement under applicable law, shall be a defense to Indemnitee's claim or create a presumption that Indemnitee has not met any particular standard of conduct or did not have any particular belief. In connection with any determination by any Reviewing Party or otherwise as to whether the Indemnitee is entitled to be indemnified hereunder under applicable law, the burden of proof shall be on the Company to establish that Indemnitee is not so entitled.

d. Notice to Insurers. If, at the time of the receipt by the Company of a notice of a Claim pursuant to Section 4(b) hereof, the Company has liability insurance in effect which may cover such Claim, the Company shall give prompt notice of the commencement of such Claim to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all reasonable or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Claim in accordance with the terms of such policies.

e. Selection of Counsel. In the event the Company shall be obligated hereunder to provide indemnification for or make any Expense Advances with respect to the Expenses of any Claim, the Company, if appropriate and with the consent of the Indemnitee (which consent shall not be unreasonably withheld), shall be entitled to assume the defense of such Claim upon the delivery to Indemnitee of written notice of the Company's election to do so. The Company shall be entitled to select legal counsel reasonably acceptable to the Indemnitee for purposes of such defense. After delivery of such notice and the retention of such counsel by the Company, the Company will not be liable to Indemnitee under this Agreement for any fees or expenses of separate counsel subsequently retained by or on behalf of Indemnitee with respect to the same Claim; provided that, (i) Indemnitee shall have the right to employ Indemnitee's separate counsel in any such Claim at Indemnitee's expense and (ii) if (A) the employment of separate counsel by Indemnitee has been previously authorized by the Company, (B) Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and Indemnitee in the conduct of any such defense, or (C) the Company shall not continue to retain such counsel to defend such Claim, then the fees and expenses of Indemnitee's separate counsel shall be Expenses for which Indemnitee may receive indemnification or Expense Advances hereunder.

5. Additional Indemnification Rights: Nonexclusivity.

a. Scope. In the event of any change after the date of this Agreement in any applicable law, statute or rule which expands the right of a Delaware (or such other state, in the case of a Subsidiary incorporated in a state other than Delaware) corporation to indemnify a member of its board of directors or an officer, employee, agent or fiduciary, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits afforded by such change. In the event of any change in any applicable law, statute or rule which narrows the right of a Delaware (or such other state, in the case of a Subsidiary incorporated in a state other than Delaware) corporation to indemnify a member of its board of directors or an officer, employee, agent or fiduciary, such change, to the extent not otherwise required by such law, statute or rule to be applied to this Agreement, shall have no effect on this Agreement or the parties' rights and obligations hereunder, except as otherwise set forth in Section 11(a).

b. Nonexclusivity. Subject to Section 7, the indemnification and the payment of Expense Advances provided by this Agreement shall be in addition to any rights to which Indemnitee may be entitled under the Company's Certificate of Incorporation (or articles of incorporation in the case of a Subsidiary incorporated in a state other than Delaware), its Bylaws, any other agreement, any vote of stockholders or disinterested directors, the Delaware General Corporation Law (or such other state's applicable business corporation law, in the case of a Subsidiary incorporated in a state other than Delaware), or otherwise. The indemnification and the payment of Expense Advances provided under this Agreement shall continue as to Indemnitee for any action taken or not taken while serving in an indemnified capacity even though subsequent thereto Indemnitee may have ceased to serve in such capacity.

6. Settlement. The Company shall have no obligation to indemnify Indemnitee under this Agreement for any amounts paid in settlement of any Claim effected without the Company's prior written consent. The Company shall not settle any Claim in any manner which would impose any fine, penalty or any obligation on Indemnitee, without Indemnitee's prior written consent. Neither the Company nor Indemnitee shall unreasonably withhold, condition or delay their consent to any proposed settlement.

7. No Duplication of Payments. The Company shall not be liable under this Agreement to make any payment in connection with any Claim made against Indemnitee to the extent Indemnitee has otherwise actually received payment (under any insurance policy, provision of the Company's Certificate of Incorporation, any applicable Subsidiary's articles of incorporation, Bylaws or otherwise) of the amounts otherwise payable hereunder.

8. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses incurred in connection with any Claim, but not, however, for all of the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion of such Expenses to which Indemnitee is entitled.

9. Mutual Acknowledgment. Both the Company and Indemnitee acknowledge that, in certain instances, federal law or applicable public policy may prohibit the Company from indemnifying its directors, officers, employees, agents or fiduciaries under this Agreement or otherwise. Indemnitee understands and acknowledges that the Company has undertaken or may be required in the future to undertake with the Securities and Exchange Commission to submit the question of indemnification to a court in certain circumstances for a determination of the Company's ability under public policy to indemnify Indemnitee.

10. Liability Insurance. To the extent the Company maintains liability insurance applicable to directors, officers, employees, agents or fiduciaries, Indemnitee shall be covered by such policies in such a manner as to provide Indemnitee the same rights and benefits as are provided to the most favorably insured of the Company's directors, if Indemnitee is a director; or of the Company's officers, if Indemnitee is not a director of the Company but is an officer; or of the Company's key employees, agents or fiduciaries, if Indemnitee is not an officer or director but is a key employee, agent or fiduciary.

11. Exceptions. Notwithstanding any other provision of this Agreement, the Company shall not be obligated pursuant to the terms of this Agreement:

a. Indemnification Prohibited by Law. To indemnify or make Expense Advances to Indemnitee with respect to Claims arising out of acts, omissions or transactions for which Indemnitee is prohibited from receiving indemnification under applicable law.

b. Fraud, Willful Misconduct or Crime. To indemnify or make Expense Advances to Indemnitee with respect to Claims arising out of acts, omissions or transactions (i) that a court having jurisdiction in such matter has finally judicially determined (as to which determination all rights of appeal therefrom have been exhausted or lapsed) constitute fraud or willful misconduct by Indemnitee; (ii) that Indemnitee has admitted in writing or under testimony constitute fraud or willful misconduct by Indemnitee; or (iii) for which Indemnitee has been convicted of a crime related to the Claim.

c. Claims Initiated by Indemnitee. To indemnify or make Expense Advances to Indemnitee with respect to Claims initiated or brought voluntarily by Indemnitee and not by way of defense, counterclaim or crossclaim, except (i) with respect to actions or proceedings brought to establish or enforce a right to indemnification under this Agreement or any other agreement or insurance policy or under the Company's Certificate of Incorporation (or articles of incorporation in the case of a Subsidiary incorporated in a state other than Delaware) or Bylaws now or hereafter in effect relating to Claims for Covered Events, or (ii) in specific cases, if the Board of Directors has approved the initiation or bringing of such Claim.

d. Lack of Good Faith. To indemnify Indemnitee for any Expenses incurred by the Indemnitee with respect to any action instituted (i) by Indemnitee to enforce or interpret this Agreement, if a court having jurisdiction over such action determines, as provided in Section 15, that the Indemnitee's action was not made in good faith or was frivolous, or (ii) by or in the name of the Company to enforce or interpret this Agreement, if a court having jurisdiction over such action determines, as provided in Section 15, that the defense asserted by Indemnitee in such action was not made in good faith or was frivolous.

e. Claims Under Section 16(b). To indemnify Indemnitee for Expenses and the payment of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 16(b) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder, or any similar successor statute, rule or regulation.

f. Non-compete and Non-disclosure. To indemnify Indemnitee in connection with proceedings or claims involving the enforcement of non-compete and/or non-disclosure agreements or the non-compete and/or non-disclosure provisions of employment, consulting or similar agreements the Indemnitee may be a party to with the Company, or any subsidiary of the Company or any other applicable foreign or domestic Company, partnership, joint venture, trust or other enterprise, if any.

12. Contribution.

a. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for herein is held by a court of competent jurisdiction to be unavailable to Indemnitee in whole or in part, it is agreed that, in such event, the Company shall, to the fullest extent permitted by law, contribute to the payment of Indemnitee's costs, charges and expenses (including attorneys' fees), judgments, fines and amounts paid in settlement with respect to any action, suit or proceeding, whether civil, criminal, administrative or investigative, in an amount that is just and equitable in the circumstances, taking into account, among other things, contributions by other directors and officers of the Company or others pursuant to indemnification agreements or otherwise; provided, that, without limiting the generality of the foregoing, such contribution shall not be required where such holding by the court is due to (i) the failure of Indemnitee to meet the standard of conduct required by applicable law, or (ii) any limitation on indemnification set forth in Sections 6, 7 or 11 hereof.

b. The Company shall not enter into any settlement of any action, suit, claim or proceeding in which the Company is jointly and severally liable with Indemnitee (or would be, if joined in such action, suit, claim or proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

c. The Company hereby agrees to fully indemnify and hold harmless Indemnitee from any and all claims for contribution which may be brought by officers, directors or employees of the Company other than Indemnitee who may be jointly liable with Indemnitee.

13. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall constitute an original.

14. Binding Effect: Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors, assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), spouses, heirs and personal and legal representatives. This Agreement shall continue in effect regardless of whether Indemnitee continues to serve as a director, officer, employee, agent or fiduciary (as applicable) of the Company or of any other enterprise at the Company's request.

15. Expenses Incurred in Action Relating to Enforcement or Interpretation. In the event that any action is instituted by Indemnitee under this Agreement or under any liability insurance policies maintained by the Company to enforce or interpret any of the terms hereof or thereof, Indemnitee shall be entitled to be indemnified for all Expenses incurred by Indemnitee with respect to such action (including without limitation attorneys' fees), regardless of whether Indemnitee is ultimately successful in such action, unless, as a part of such action, a court having jurisdiction over such action makes a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee's action was not made in good faith or was frivolous; provided, however, that until such final judicial determination is made, Indemnitee shall be entitled under Section 3 to receive payment of Expense Advances hereunder with respect to such action. In the event of an action instituted by or in the name of the Company under this Agreement to enforce or interpret any of the terms of this Agreement, Indemnitee shall be entitled to be indemnified for all Expenses incurred by Indemnitee in defense of such action (including without limitation costs and expenses incurred with respect to Indemnitee's counterclaims and cross-claims made in such action), unless, as a part of such action, a court having jurisdiction over such action makes a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that the defense asserted by Indemnitee in such action was not made in good faith or was frivolous; provided, however, that until such final judicial determination is made, Indemnitee shall be entitled under Section 3 to receive payment of Expense Advances hereunder with respect to such action.

16. Period of Limitations. Except for legal actions based on Indemnitee's fraud or willful misconduct as to which the period of limitations shall be governed by applicable law, no legal action shall be brought and no cause of action shall be asserted by or in the right of the Company against Indemnitee, Indemnitee's estate, spouse, heirs, executors or personal or legal representatives after the expiration of two years from the date of accrual of such cause of action, and any claim or cause of action of the Company shall be extinguished and deemed released unless asserted by the timely filing of a legal action within such two year period; provided, however, that if any shorter period of limitations is otherwise applicable to any such cause of action, such shorter period shall govern.

17. Term. All agreements and obligations of the Company contained in this Agreement shall continue during the period Indemnitee serves as a director or officer of the Company or, at the request of the Company (or any wholly owned subsidiary of the Company), serves as a director, officer, employee or agent (which, for purposes hereof, shall include a trustee, fiduciary, partner or manager or similar capacity) of another company (including any subsidiaries of the Company), partnership, joint venture, trust, employee benefit plan or other enterprise, and shall continue thereafter so long as Indemnitee may be subject to any possible action, suit, claim or proceeding (including any rights of appeal thereto and any proceeding commenced by Indemnitee pursuant to Section 2(c) or Section 15 hereof) by reason of Indemnitee's service described herein, whether or not Indemnitee is acting in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement.

18. Notice. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed duly given (i) on the date of delivery if delivered by hand and signed for by the party addressed; (ii) on the third business day after the date postmarked if mailed by domestic certified or registered mail with postage prepaid; or (iii) one (1) business day after deposit with a nationally recognized overnight courier, specifying next day delivery. Addresses for notice to either party are as shown on the signature page of this Agreement, or as subsequently modified by written notice.

19. Consent to Jurisdiction. The Company and Indemnitee each hereby irrevocably consent to the jurisdiction of the courts of the State of Delaware for all purposes in connection with any action or proceeding which arises out of or relates to this Agreement and agree that any action instituted under this Agreement shall be commenced, prosecuted and continued only in the Court of Chancery of the State of Delaware in and for New Castle County, which shall be the exclusive and only proper forum for adjudicating such a claim.

20. Severability. The provisions of this Agreement shall be severable in the event that any of the provisions hereof (including any provision within a single section, paragraph or sentence) are held by a court of competent jurisdiction to be invalid, void or otherwise unenforceable, and the remaining provisions shall remain enforceable to the fullest extent permitted by law. Furthermore, to the fullest extent possible, the provisions of this Agreement (including without limitation each portion of this Agreement containing any provision held to be invalid, void or otherwise unenforceable, that is not itself invalid, void or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.

21. Choice of Law. This Agreement, and all rights, remedies, liabilities, powers and duties of the parties to this Agreement, shall be governed by and construed in accordance with the laws of the State of Delaware as applied to contracts between Delaware residents entered into and to be performed entirely in the State of Delaware without regard to principles of conflicts of laws.

22. Subrogation. In the event of payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all documents required and shall do all acts that may be necessary to secure such rights and to enable the Company effectively to bring suit to enforce such rights.

23. Amendment and Termination. No amendment, modification, termination or cancellation of this Agreement shall be effective unless it is in writing signed by both the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed to be or shall constitute a waiver of any other provisions hereof (whether or not similar), nor shall such waiver constitute a continuing waiver.

24. Integration and Entire Agreement. This Agreement sets forth the entire understanding between the parties hereto and supersedes and merges all previous written and oral negotiations, commitments, understandings and agreements relating to the subject matter hereof between the parties hereto.

25. No Construction as Employment Agreement; Conflicts with Employment Agreements. Nothing contained in this Agreement shall be construed as giving Indemnitee any right to be retained in the employ of the Company or any of its Subsidiaries or affiliated entities. In the event the Indemnitee is a party to an Employment Agreement with the Company or any of its subsidiaries or affiliated entities and the terms of this Agreement conflict with the terms of the Employment Agreement, the Employment Agreement shall control and this Agreement shall be deemed modified to the extent necessary to give effect to the terms of the Employment Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement as of the date first above written.

MELA SCIENCES, INC.

By: _____
Name:
Title:

Address: 50 S. Buckhout Street, Suite 1
Irvington, NY 10533

AGREED TO AND ACCEPTED:

INDEMNITEE:

_____
Name:

Address: _____

_____

Exhibit 10.23

MELA Sciences, Inc.
50 S. Buckhout Street, Suite 1
Irvington, NY 10536

February 5, 2014

Broadfin Healthcare Master Fund, LTD
221 Park Avenue, 9th Floor
New York, NY 10017

RE: Director Designation Right

Ladies and Gentlemen:

Reference is made to that certain Securities Purchase Agreement dated January 31, 2014 between MELA Sciences, Inc. (the "Company") and the purchasers listed on the signature pages thereto (the "Purchase Agreement") pursuant to which certain funds managed by Sabby Management, LLC and Broadfin Capital, LLC ("Broadfin") are purchasing certain securities of the Company.

In connection with the Purchase Agreement and subject to the below paragraph, effective upon the closing of the transactions contemplated by the Purchase Agreement the Company agrees that it will appoint to its Board of Directors a director designated in writing by Broadfin (such designee and as such designee may be replaced as provided herein, the "Designee") within five days of such designation. Further, subject to the paragraph below, for so long as Broadfin retains the warrant issued pursuant to the Purchase Agreement or at least 30% of the Series A Preferred Stock (as defined in the Purchase Agreement) originally purchased (or shares of common stock into which such Series A Preferred Stock was converted) then the Company shall continue to recommend to its stockholders that it elect the Designee to serve as a director on the Company's Board. The Company further agrees that it will not take action to remove, or recommend the removal of, the Designee without cause therefore. Upon any removal or resignation of the Designee, the Company shall, within five days of the receipt of written notice from Broadfin of the identification of a replacement designee, appoint to fill the vacancy so created with such replacement designee subject to the paragraph below. The Designee, once a Director of the Company, shall be entitled to all of the rights enjoyed by other non-employee Directors of the Company, including receipt of information, reimbursement of expenses and coverage under applicable director and officer insurance polices.

Further, Broadfin agrees that it will not propose any individual as the Designee to be a member of the Company's Board of Directors whose background does not comply with or would disqualify the Company from complying with (i) applicable securities laws, (ii) contractual obligations to and rules of The Nasdaq Stock Market, and (iii) the criteria for directors set forth in the then current charter of the Company's Nominating Committee, and will not disqualify the Company from being able to conduct any public offering or private placement pursuant to either Rule 506 (b) or (c) and any "bad boy" provisions of any state securities laws. To the extent that any Designee who becomes a director and does not satisfy the conditions of the preceding sentence, that person will immediately resign, and Broadfin will have the right to propose a
replacement person to fill such vacancy otherwise in accordance with the terms of this agreement.

Very truly yours,

MELA Sciences, Inc.

/s/ Rose Crane

Rose Crane
Chief Executive Officer

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 and File No. 333-189118) and on Forms S-8 (File No. 333-136183 and File No. 333-161286 and File No. 333-189119) of our report dated March 17, 2014 with respect to our audits of the balance sheets of MELA Sciences, Inc. as of December 31, 2013 and 2012, and the related statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2013 included in the December 31, 2013 annual report on Form 10-K of MELA Sciences, Inc.

Our report dated March 17, 2014 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 17, 2014

Exhibit 31.1

CERTIFICATION

I, Rose Crane, 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/ Rose Crane
Rose Crane
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 17, 2014

Exhibit 31.2

CERTIFICATION

I, Mary Phelan, 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/ Mary Phelan
Mary Phelan
Controller
(Principal Accounting and Financial Officer)

Date: March 17, 2014

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 her knowledge that the Company's Annual Report on Form 10-K for the period ended December 31, 2013 (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/ Rose Crane
Rose Crane
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

March 17, 2014

/s/ Mary Phelan
Mary Phelan
Controller
(Principal Accounting and Financial Officer)

March 17, 2014

* 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.