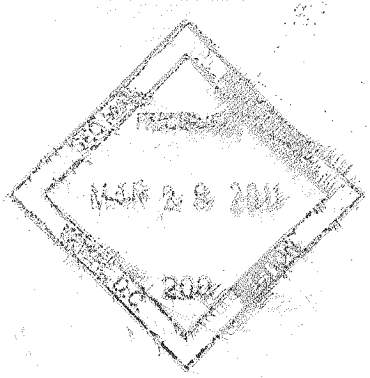
MELA™ Sciences

2010 Annual Report

Committed to changing the face of melanoma



Dear Shareholder:

One of the most humbling and exciting events in the history of our company occurred on November 18, 2010. A team from among the world's leading dermatologists, dermatopathologists and statisticians, along with the MELA Sciences clinical group and I, went before a Panel of experts appointed by the U.S. Food and Drug Administration (FDA) to present our case that MelaFind® has the potential to help dermatologists detect melanoma at its earliest, most curable stages.

World-renowned melanoma experts, which included former presidents of the most prestigious dermatology societies, presented our data and spoke at the open public forum session. Also speaking at the open public session in support of MelaFind were two top dermatologists whose lives were personally impacted by melanoma: one having lost a close friend to this disease that kills one American each hour, and the other herself being a melanoma survivor.

We were thrilled when the FDA-appointed Panel voted favorably on all three questions put to it by the Agency regarding MelaFind. The FDA is not required to accept the recommendation of the Panel, but we remain steadfast in our goal to market MelaFind in the U.S. and countries around the world that are deeply impacted by melanoma.

Just like the experts who spoke on our behalf to the Panel, we understand the grave severity of this disease. With no cure for advanced melanoma, early detection is the greatest defense – and our greatest aspiration. Experts have long told us that they need more effective tools to help them identify melanoma at the earliest, most curable stages.

We've dedicated over a decade to developing a device that recognizes and analyzes the characteristics of early melanoma beyond what's visible to the human eye. We believe the additional information that today's MelaFind system provides will offer dermatologists a tool to help them make better decisions as to whether or not to biopsy indeterminate lesions.

Our MelaFind pre-market approval application (PMA) is based on the positive results of our landmark pivotal study, which included 1,831 pigmented skin lesions from 1,383 patients, making this the largest prospective study ever conducted in melanoma detection. In October 2010, the data from the MelaFind pivotal study were published in the *Archives of Dermatology*, the premier peer-reviewed medical journal in dermatology. The data showed MelaFind was able to detect over 98% of the melanomas in the study, while ruling out benign lesions at a better rate than the dermatologists who participated in the study.

It has always been our intention to market MelaFind to dermatologists. In February 2011, we submitted an amendment to the PMA that clarifies our intentions and limits the use of MelaFind in the U.S. to dermatologists, based on discussions during the Panel meeting. If MelaFind is approved by the FDA, we intend to initially pursue a regional launch in the New York Tri-State Area, where high melanoma rates and a high concentration of top dermatology practices make it an ideal market for a breakthrough early melanoma detection tool.

Melanoma is certainly not only a problem in the U.S. With that in mind, we are working on our application for a CE Mark that will allow us to market MelaFind in the European Union. We are currently looking to the German market as a first priority since it has one of the strongest economies in Europe and a large portion of the patient population is vulnerable to this deadly disease.

I would like to offer my sincere thanks to the dermatologists, physicians and nurses who have worked with us in our clinical trials and who offered their impassioned pleas at the Panel meeting for better tools to aid in the detection of early melanoma; our employees who have worked tirelessly to develop this product; and especially our shareholders for standing by us through the long regulatory process. I want to assure healthcare practitioners and patients that we will continue to do all that we can do to secure FDA approval of MelaFind so that we may help bring about the day when Americans no longer die of this disease at the rate of one per hour.

We are committed and dedicated to changing the face of this disease and look forward to working with regulators, dermatologists and patients to make our quest a reality.

Sincerely,

Joseph V. Gulfo, MD
President and Chief Executive Officer
MELA Sciences

March 23, 2011

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, 2010

☐ **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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a 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 21,910,653 shares of common stock held by non-affiliates of the registrant as of June 30, 2010 was $163,015,258 based on the last reported sale price of $7.44 per share on the Nasdaq Capital Market on June 30, 2010. (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 5.1% 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. There were no shareholders holding at least 10% of the Company's common stock). The number of shares outstanding of the registrant's common stock as of February 28, 2011 was 25,262,538 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2011 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.

2010 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 design, development and commercialization of a non-invasive, point-of-care (i.e. in the doctor's office) instrument to aid in the detection of early melanoma. Our flagship product, MelaFind®, features a hand-held imaging device that emits light of multiple wavelengths to capture images of suspicious pigmented skin lesions and extract data. The data are then analyzed utilizing image processing classification algorithms, 'trained' on our proprietary database of melanomas and benign lesions, to provide 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 imaging device*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- our *proprietary database* of pigmented skin lesions, which we believe to be the largest in the US; and
- our *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions.

The MelaFind® Pre-Market Approval ("PMA") application was submitted in June 2009 and is under review at the U.S. Food and Drug Administration ("FDA"). A pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a Protocol Agreement. In addition, the MelaFind® PMA has been granted expedited review by the FDA.

On November 18, 2010, the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel ("Panel"). The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on the FDA. In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendment.

Upon obtaining approval from the FDA, we plan to launch MelaFind® commercially in the United States.

Also in 2010, the Company initiated steps toward being able to introduce the MelaFind® device commercially in Europe. The Company is actively planning representation, conducting market research activities and working with European regulatory agencies on achieving Conformite Europeenne ("CE") marking of MelaFind®.

To date the Company has not generated any revenues from MelaFind®.

Skin cancer is the most common form of cancer in the United States. More than 3.5 million skin cancers in over two 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. It is estimated that more than 114,000 new cases of melanoma were diagnosed in the U.S. in 2010 — more than 46,000 non-invasive (*in situ*) and more than 68,000 invasive, with nearly 8,700 resulting in death — and a similar number of new cases is projected for 2011. This has resulted in melanoma being the cause of one death every hour of every day of the year in the U.S. Melanoma is responsible for approximately 75% of skin cancer fatalities and is the deadliest of all skin cancers as 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, early 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 melanoma *in situ* stage.

Because detection of early melanoma is critical to survival, the American Cancer Society recommends that all Americans over the age of 20 undergo complete skin examinations during their periodic health check-ups. Individuals with dysplastic nevi, a type of pigmented skin lesion associated with an increased risk of melanoma, warrant more frequent observation.

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.

MELA Sciences 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 reconstructed Red Green Blue ("RGB") digital images of pigmented skin lesions. It uses automatic image analysis and statistical pattern recognition to help identify lesions to be considered for biopsy to rule out melanoma, the deadliest form of skin cancer.

To date, MelaFind® has been developed, trained and tested on a proprietary database of over 10,000 skin lesions from more than 7,000 patients at over 40 clinics. The Company believes this is the largest such database in the U.S. and a substantial barrier to competition. The landmark MelaFind® pivotal trial, the largest prospective clinical study ever conducted in melanoma detection, achieved sensitivity of greater than 95% (95% lower confidence bound) and specificity statistically significantly higher than that of study clinicians.

We believe that with the assistance provided by MelaFind®, dermatologists could diagnose more melanomas at the earliest, most curable stages with fewer false positive biopsies, which would reduce both treatment costs and the number of unnecessary biopsies, and improve quality of life.

Our objective 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 2 million projected cases annually, and is estimated to account for almost 50% of all cancers. Melanoma is the deadliest form of skin cancer and in 2010 accounted for an estimated 8,700 deaths. It is estimated that more than 114,000 new cases of melanoma were diagnosed in the U.S. in 2010 — more than 46,000 non-invasive (*in situ*) and more than 68,000 invasive, with similar numbers projected for 2011. There are three significant forms of skin cancer: basal cell, accounting for approximately 75% of skin cancer cases; squamous cell, totaling approximately 20% of skin cancer cases; and melanoma, which accounts for an estimated 4% of skin cancer cases, but is responsible for approximately 75% of all deaths from skin cancer.

The American Cancer Society projects over 10,000 deaths annually from all types of skin cancer. Since 1973, the mortality rate for melanoma has increased by 50%. Because approximately 62% of melanomas and 45% of melanoma deaths occur prior to age 65, melanoma places significant burdens on the healthcare system well beyond Medicare.

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*," it has a survival rate of 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. Metastases 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 is difficult to treat. At this advanced stage, the five year survival rate is about 15% to 20%. Moreover, survival prospects for those with advanced melanoma have not improved over the past three decades.

In terms of incidence, melanoma is currently the fastest growing cancer and the subject of significant attention in the medical community. A publication from the National Cancer Institute (report published in the July 10, 2008 online edition of the *Journal of Investigative Dermatology*) indicates that the annual incidence of melanoma among young adult Caucasian women rose 50% between 1980 and 2004. 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 women aged 25 to 29 and the number-one cancer killer of women ages 30 to 35. Melanoma is virtually 100% curable if caught early, though no cure is currently available for advanced-stage melanoma.

Our Strategy

Our objective is for MelaFind® to become an integral part of the standard of care in melanoma detection. To achieve this objective, we are pursuing the following strategy:

- Establish MelaFind® *as the leading technology for aiding in the detection of early melanoma.* We have invested considerable capital and expertise into developing our core technology platform, which is protected by twelve U.S. and two Australian patents. We will continue to refine and optimize this technology in order to position MelaFind® as the leading system for aiding in the detection of early melanoma.

- *Pursue the timely FDA approval of MelaFind®.* We entered into a binding Protocol Agreement with the U.S. Food and Drug Administration ("FDA"), which is an agreement for the conduct of the pivotal trial in order to establish the safety and effectiveness of MelaFind®. The FDA has informed us that the MelaFind® pre-market approval, or PMA, application would receive expedited review. On November 18, 2010, the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel. The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on the FDA. In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendment. Upon obtaining PMA approval from the FDA, we plan to launch MelaFind® commercially in the United States.

- *Commercialize MelaFind® using multiple sales and marketing strategies.* We intend to commence commercialization of MelaFind® in selected U.S. markets immediately upon receiving PMA approval from the FDA and internationally upon achieving CE marking and regulatory review. Our marketing effort will focus initially on "high" volume, integrated dermatology practices and skin cancer specialists, in key regions of the U.S. and Europe. To enter the larger general dermatology markets in the U.S., and internationally, we may establish partnerships with pharmaceutical and/or diagnostic/device companies which have an established presence in these markets. The plan is for dermatologists to offer their patients examinations with MelaFind® on a self-pay per patient basis creating a recurring revenue

stream. Once there is sufficient evidence to support favorable coding and coverage decisions and to obtain appropriate payment levels, we may pursue national coverage decisions from the Centers for Medicare and Medicaid Services ("CMS") and private payers for third-party reimbursement.

Additionally, our strategy may include the potential acquisition of complementary products and technologies in the dermatological arena.

Limitations of Current Melanoma Diagnosis

Melanomas are 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 suspicious skin lesion under evaluation. Further, clinical examination is limited to the surface appearance of the suspicious 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 unnecessary biopsies of benign lesions, but even dermoscopy experts biopsy 3-10 benign lesions for every melanoma detected. While many primary care physicians immediately refer patients with suspicious 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 early melanoma. The MelaFind® system in commercial use will produce a report at the-point-of-care to aid in the diagnostic process. The system is comprised of a hand-held imaging device, our proprietary database of pigmented skin lesions and our lesion classifiers. MelaFind® employs multiple wavelengths of light to obtain data from images of suspicious lesions; and then the data are analyzed against our proprietary database of melanomas and benign lesions using our sophisticated algorithms. The MelaFind® report will contain objective information about the lesion that may not be otherwise available, including information useful in making the decision to biopsy the lesion. The key components of the MelaFind® system are:

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

- an illuminator that shines 10 different specific wavelengths of light, including near infra-red bands;
- a lens system composed of nine elements that creates images of the light reflected from the lesions;
- a photon (light) sensor; and
- an image processor employing proprietary algorithms to extract many discrete characteristics or features from the images.

Our proprietary database of pigmented skin lesions, which includes *in vivo* MelaFind® images 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 US 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 imaging device. The *Lesion Classifiers* are developed from our proprietary database of pigmented skin lesions and employ sophisticated mathematical algorithms. 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 the *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 commercial use.

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 History

In 2004, we entered into a binding Protocol Agreement with the FDA for our pivotal clinical trial. A pivotal clinical trial is a blinded clinical study that is used by the FDA as the basis for determining the effectiveness of a device in a PMA application. The Protocol Agreement specified the inclusion criteria (description of patients and lesions eligible for the trial), sample size, endpoints, and performance criteria necessary to establish the safety and effectiveness of MelaFind®. The Protocol Agreement required that the study include at least 1,200 pigmented skin lesions and at least 93 eligible melanomas for analysis.

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. We have not been required to file an IDE application for the MelaFind® clinical studies because the FDA has considered them to be "Non-Significant Risk" ("NSR") studies subject to abbreviated IDE regulations, which do not require formal IDE submission. 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 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. 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. Although we believe our clinical trial satisfies the FDA Protocol Agreement, it may ultimately be determined to be inadequate to support approval of a PMA application.

The MelaFind® pivotal clinical trial was conducted at seven centers across the U.S. and included 1,831 pigmented skin lesions from 1,383 patients. Prior to the start of the study, the Company and the FDA entered into a binding Protocol Agreement to stipulate the sensitivity and specificity endpoints that should 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 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-value less than 0.02). The Protocol Agreement calls 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, variability was observed in dermatologists' decisions to biopsy, measured with a kappa score of 0.29. This indicates that dermatologists often did not elect to biopsy the same lesions as other dermatologists participating in the study (note: a kappa score of 1.0 would indicate perfect agreement, while a score of 0.0 indicates no agreement).

We submitted our PMA application, which includes the final study reports, to the FDA on June 9, 2009. The FDA has informed us that the MelaFind® PMA application would receive Expedited Review. On November 18, 2010, the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel ("Panel"). The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on the FDA. In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendment.

Although we believe our clinical trial provides favorable data to support our PMA application, upon evaluation the FDA may conclude differently. Delays in receipt of or failure to receive FDA approval, 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. Even if granted, the approvals may include significant limitations on the intended use and indications for use for which our products may be marketed.

Hardware and Software History

ASKION GmbH ("ASKION"), located in Germany, which specializes in precision optics, has become an integral member of our MelaFind® development team and we expect to continue to work with ASKION for the foreseeable future. ASKION produced the MelaFind® hand-held imaging devices used in our pivotal clinical trials and is currently building additional units and performing other additional developmental activities on our behalf.

Through ASKION, the Company uses Carl Zeiss Jena GmbH ("Zeiss") to build the lenses and lens assemblies that are being used in MelaFind® system. In addition, Zeiss provides the Company with certain technical consulting expertise for production scale-up of the MelaFind® systems.

In developing the MelaFind® system, we have developed and tested several generations of hand-held imaging devices. Commercial-grade systems were used in our pivotal clinical trial. MelaFind® has been developed, trained and tested on over 10,000 skin lesions from over 7,000 patients at over 40 clinical sites.

The Company has obtained Underwriters' Laboratories ("UL") certification and Certification Bodies' Scheme ("CB") test certification for MelaFind®. For commercialization outside the U.S., approvals from appropriate regulatory bodies within other countries will be required. The CB test certification is an international system of acceptance for test reports and facilitates the process of obtaining product certification

in many other countries We have also begun the process of seeking the CE mark approval for MelaFind®in the European Union.

MelaFind® Sales and Marketing

Upon FDA approval, we plan to offer MelaFind® as a point-of-care service. This approach is intended to provide U.S. with recurring revenue corresponding to the number of patients examined and to provide the physician with access to our technology without a significant capital investment. Our sales and marketing strategy is to establish a regionally focused sales, marketing, and distribution effort in the U.S. and Europe. We plan to concentrate our commercialization efforts initially on "high volume", integrated dermatology practices and skin cancer experts in key regions of the U.S. and Europe. For expansion to the general dermatology markets, we may establish partnerships to accelerate the product introduction and to maximize the breadth of the commercial opportunity. While we are exploring potential partnership opportunities we have not yet established any such arrangements.

The MelaFind® Value Proposition for the Healthcare System

We plan to offer MelaFind® on a self-pay (non-reimbursed) basis. Based on market research with physicians and patients, we believe that a self-pay model could support significant utilization of MelaFind® in the dermatologists' offices.

Following the self-pay introduction of MelaFind®, we will look to build a sufficient body of medical evidence to support favorable coding and coverage decisions at appropriate payment levels by third-party payers. This strategy is consistent with the approach that has been used to support positive coverage decisions by CMS and private payers for other products. The value drivers include the detection of melanoma at the early curable stages, as opposed to advanced stages, allowing for both a greater opportunity to cure and a reduction in treatment costs.

Our Reimbursement Strategy

We may pursue Current Procedural Terminology ("CPT") code and private insurance coverage, as appropriate, following initial commercialization efforts, which will be undertaken on a self-pay basis. 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 our 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 (Evidence-Based Medicine), 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. Upon FDA approval of MelaFind®, we will consider submitting 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 commercial

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 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. We believe it is likely that initially the private payers, managed care organizations, and state Medicare administrative contractors will desire to establish pilot programs of MelaFind® to determine the impact of the product in their systems.

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. Likewise, we believe that once patients become aware of the availability of MelaFind®, they may request that their physicians utilize MelaFind®. We believe that MelaFind® will represent an improvement in the standard of care for the early 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 including the American Academy of Dermatology annual and regional 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. We also plan to sponsor clinical trials following FDA PMA approval in order to evaluate MelaFind® in additional settings. 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 will 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 plan to employ an active strategy to obtain medical coverage, identify appropriate coding and establish adequate payment.

Competition

We are not aware of any system which is directly competitive to MelaFind®. 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"), digital dermoscopes, spectrophotometric intercutaneous analysis (analysis of skin structures through measurement of how they absorb light of different wavelengths), 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.

The current primary method for detecting melanoma relies on physicians to interpret whether a pigmented skin lesion is suspicious for melanoma (thereby requiring biopsy) based on their ability to recognize patterns using clinical examination. Physicians use the "ABCDE" criteria: Asymmetry, Border irregularity, Color variation, Diameter greater than 6 mm, and Evolving-change in "ABCD", in their assessment. Recently the letters "PRU" have been added to the criteria; Patient concern, Regression and Ugly duckling. Physicians also use whole body mole mapping which 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. DigitalDerm, Inc. offers MoleMapCD®a computerized system for acquisition, storage, and review of the pictures and Melanoscan, Inc. offers a similar sequential photography system.

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) 3Gen, LLC (U.S.), and others. Several manufacturers have recently introduced apps that allow an Apple iPhone to be used as a dermoscope .

Digital dermoscopes allow for dermoscopic images to be visualized on a computer screen at larger magnification. In addition, images may be stored and compared to images taken previously. Manufacturers of digital dermoscopes include (but are not limited to) Derma Medical Systems, Inc. (Austria), manufacturers of the Molemax™ family of digital systems, Biomips Engineering (Italy) and FotoFinder Systems, GmbH the manufacturers of the FotoFinder group of instruments.

Dermoscopy is a tool used by approximately 25% of dermatologists in the U.S. and is associated with a long learning curve. Physicians experienced in the use of dermoscopy have been shown to have an increased diagnostic accuracy of 10 to 20% over clinical examination. Although some digital dermoscopes provide information regarding the probability that a lesion may be melanoma compared to a database of lesions, no system, to our knowledge, is under PMA development for objective interpretation.

Spectrophotometric intercutaneous analysis is a technique of visualizing collagen, blood, and pigment. Biocompatibles International (UK) manufactures the Siascope a device utilizing this technique. Working in conjunction with the Company's MoleMate software the system produces a rating "score" for scanned lesions.

Confocal microscopy is an approach for non-invasive visualization of skin structures at the cellular level; such a device utilizing this technique is in development by Lucid, Inc. (U.S.). Researchers at Vanderbilt University are developing technology called 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. In addition, Verisante Technology, Inc. formerly T-Ray Science, Inc. is developing technology it has licensed from The British Columbia Cancer Agency, an agency of the Provincial Health Services Authority for skin cancer detection. The company's product, Verisante Aura, uses NIR Raman Spectroscopy and autofluorescence spectroscopy to measure 21 biomarkers for skin cancer in half a second and results published in 2008 showed a sensitivity of 100% and specificity of 70% for melanoma.

Other imaging modalities, including molecular imaging in which tagged antibodies search for cancer cell antigens, and molecular and genetic screening tests. Molecular-based approaches are also being investigated; for example Dermtech, Inc. is exploring Messenger RNA analysis of surface cells. The company's core technologies are 1) the patented, non-invasive EGIR™ (Epidermal Genetic Information Retrieval) 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. To date, the company has patented three biomarkers that can be used to identify and correlate changes in the gene expression profile of RNA obtained from the skin with the presence of certain diseases.

Scibase AB is developing electrical impedance technology for melanoma detection. The method is called electrical impedance spectroscopy (EIS). It is based on a technology that uses the varying electrical properties of human tissue to categorize the cell structures and thereby detect malignancies. The company recently completed a 1,200 patient clinical trial and announced that results from their studies show that it is possible to separate benign moles from malignant with a "sensitivity exceeding 98% and specificity over 20% better than study dermatologists."

Several additional light based imaging approaches have recently been identified.

Balter Medical (Norway) uses 'Optical Transfer Diagnosis' to identify melanomas. The technology measures how much light is absorbed in healthy versus diseased tissue to determine whether cancer is present.

Raytheon Corporation, has partnered with Arizona Cancer Center, to utilize satellite-based remote imaging technology in detecting skin changes that could indicate the presence of cancer.

Researchers at Ben Gurion University in Israel announced a new device that detects cancerous skin tumors not visible to the naked eye. The Optical Spectro-Polarimetric Imaging (OSPI) instrument reportedly diagnosed 73 types of lesions, some of them cancerous, in initial testing.

Michelson Diagnostics Ltd, a UK based developer and manufacturer of Optical Coherence Tomography (OCT) products, has US FDA 510(k) clearance for its VivoSight[tm] OCT scanning product. VivoSight[tm] is a Multi-Beam OCT system indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body. VivoSight[tm] is a Fourier-Domain OCT scanner that provides 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 and in real time, using an easy-to-use lightweight hand-held probe.

mBeach Software (U.S.) through its wholly owned subsidiary Skin Cancer Scanning Ltd. is developing SkinScan 650 a device that currently uses reflected visual light to analyze non-melanoma lesions. The company reported that its initial 128 lesion trial produced an "accuracy" of 92.4%.

Cascade Technologies Corp through its wholly owned subsidiary Spectral Molecular Imaging (a development stage company) is using what it calls "hyperspectral-optical technology to advance early and accurate diagnosis of cancer and pre-cancer conditions. The company's SkinSpect™ device is being developed for non-invasive diagnosis of and screening for skin cancer.

The University of Missouri at Rolla announced during 2010 that it had received a new patent titled: "Automatic Detection of Critical Dermoscopy Features for Malignant Melanoma Diagnosis." The patent applies to a method for computer-aided analysis of photographs of skin lesions to detect the cancer. This method uses a traditional RGB image as its computer source.

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. If our products are approved for marketing, 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®.

Manufacturing

We are currently focusing our manufacturing efforts on building MelaFind® systems and in optimizing efficiency and larger-scale manufacturing. For this crucial phase leading up to the commercial launch of MelaFind®, we have contracted with ASKION in Germany, ISO 9001 and ISO 13485 certified, which specializes in precision optics. Through ASKION, we have contracted with Zeiss, an international optics house, to supply lenses and lens assemblies to be used in the hand-held imaging devices.

In addition, we are utilizing Nexcore Technology Inc., an FDA GMP compliant and ISO 9001 certified and ISO 13485 original equipment manufacturer of medical devices in New Jersey, to provide the assembled MelaFind® carts and tested MelaFind® systems incorporating the hand-held devices along with the processing computer, software and operator controls.

Research and Development Efforts

We continue to develop refinements and improvements to the hardware and software, including lesion classification algorithms, some of which are likely to require approval of a PMA supplement. Our R&D plan also includes further improvements such as faster and easier software downloads for future versions.

We have performed feasibility studies of a MelaFind® software add-on feature called MelaMeter™, an enhancement to MelaFind® that provides information regarding the depth of penetration of a pigmented skin lesion. This information may be useful to dermatologists in determining the necessary depth and breadth of a biopsy of a pigmented skin lesion. Initial clinical studies of MelaMeter™ demonstrate the ability of MelaMeter™ to non-invasively estimate the Breslow thickness (the thickness of a cutaneous malignant melanoma measured from the epidermis to the deepest malignant cells present) comparably to histological examination of excised lesions. We plan to continue the development of MelaMeter™ and seek FDA approval for it after receiving PMA approval of MelaFind®.

We further intend to explore and evaluate the potential use of our light based computer vision platform in other applications, including the non-invasive detection of basal cell carcinoma, the most common skin cancer, as well as squamous cell carcinoma of the skin. New hardware systems for the imaging of blood and blood vessel patterns are needed since the majority of these cancers are not pigmented and, accordingly, the MelaFind® system as currently developed is not appropriate for these uses. However, we believe many software programs and algorithms used in the MelaFind® system will be applicable with some modification.

The Company spent approximately $12,508,000, $10,950,000 and $11,497,000 in each of 2008, 2009 and 2010, respectively, on research and development.

Intellectual Property

Our policy is to protect our intellectual property by obtaining U.S. and foreign patents to protect technology, inventions and improvements important to the development of our business. Currently, we have eighteen issued U.S. patents in force, plus one that is projected to issue in the first quarter of 2011, and these patents have numerous foreign counterparts issued and pending. Of those issued, twelve U.S. patents and two Australian patents relate to various aspects of MelaFind®. Two of the U.S. patents are design patents, while all others are utility patents. In addition, we have twelve more 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, while five are pending in Australia, four in Canada, and three each in Japan and 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 the discontinuation of DIFOTI operations .

We cannot be certain that our patents will not be challenged or circumvented by competitors. Whether a patent is infringed and 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 patents, patent applications and/or other intellectual property rights would be upheld. If one or more of those patents, patent applications or other intellectual property rights are invalidated, rejected or found unenforceable, that could reduce or eliminate any competitive advantage.

We will 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 following marks: "MelaFind®" (both word and word-plus-design marks) and the former corporate logo for "eos-electro-optical sciences, inc." For MelaFind®, the description of goods in International Class 10 covered by the trademark is: "medical devices, namely, electro-optical devices incorporating hardware 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." The MELAFIND word mark has also been registered in the European Union, Australia and New Zealand. In Europe, besides International Class 10, that mark is also registered in International Classes 16 (for printed reports) and 44 (as a service mark). For "eos-electro-optical sciences, inc.," the description of goods covered by the trademark in International Class 10 is: "instrumentation comprising computer assisted optical imagers and image analyzers for use in the detection of dental cavities, cutaneous melanoma, and other pathologies of the teeth, skin and other tissues." Several additional trademark and service mark registrations are pending in the U.S. in International Classes 9, 10, 16 and 44, for which Notices of Allowance have been received but for which no Statements of Use have yet been filed. Those additional marks include the "MELA" and "MELA SCIENCES" word marks as well as the MELA Sciences corporate logo, for example. The "MELA" word mark, which has intent-to-use status in the U.S., is already registered in the European Union as well as in Australia, in International Classes 9, 10, 16 and 44. The "MELA SCIENCES" word mark, which has intent-to-use status in the U.S. in International Classes 9, 10, 16 and 44, has a corresponding Madrid Protocol application pending, which designates the European Union and Australia.

We also have registered the internet domain names: www.melasciences.com, www.eo-sciences.com, www.eosciences.com, www.melafind.com, www.mela.us.com, www.melafind.info, www.melafind.net,

www.melafind.org, www.melafind.us, melafinder.com, www.melainc.com, www.difoti.com and www.skinsurf.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
6,307,957	Multispectral Imaging and Characterization of Biological Tissue	10/23/01	06/27/20
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	03/11/25
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	03/19/29

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
US2009/0154781A1	Characterizing a Texture of an Image	12/14/07
US2009/0060304A1	Dermatology Information	09/04/08
WO2009/079367A1	Characterizing a Texture of an Image (CIP)	12/12/08
US2011/0025007 A1	Medical Cart	07/30/09
US2011/0024507 A1	Storage Card	07/30/09
WO2011/014614A2	Medical Cart (CIP)	07/29/10
WO2011/014656A2	Storage Cart (CIP)	07/29/10
TBP 02/09/12	Assessing Features for Classification	08/06/10
TBP 03/17/11	Characterizing a Texture of an Image (CIP)	09/07/10
US2011/0019888A1	Reducing Noise in Digital Images (CIP)	10/06/10
TBP 05/05/11	Showing Skin Lesion Information	11/01/10

Note: CIP denotes a Continuation-in-Part patent application; TBP = scheduled to be published on date shown

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 an image 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 in building MelaFind® classification algorithms involving the use of novel features of multispectral lesion images 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 wavelets and non-wavelets features improves significantly the sensitivity and specificity of the melanoma classifiers. Patent No. 6,307,957 extends

the use of the novel features of the MelaFind® system to endoscopy (examination of gastro-intestinal tissues using fiber-optic probes). We have no present plans to develop endoscopy applications of our technology.

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 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 is a process that we may employ to compensate for the effect of temperature-dependent dark current on the images acquired by the MelaFind® hand-held probe, and Patent No. 7,127,094 is a series of methods for central control of the acquisition and processing of the image data acquired by MelaFind® probes located at remotes sites. Patent No. 7,813,586 covers a novel method for reducing noise in digital images, which was invented and has been implemented as part of the calibration of all MelaFind® images. The two design patents describe novel design aspects of the medical cart associated with MelaFind®. The two patent applications filed on July 30, 2009 and their Continuation-in-Part applications filed on July 29, 2010, seek to protect the innovative functional aspects of the design of the medical cart and of the Patient Card used with MelaFind®, respectively.

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. Our June 12, 2007 patent filing relates to innovative ways to control use of our MelaFind® system, while our December 14, 2007 filing and its December 12, 2008 and September 7, 2010 Continuation-in-Part applications relate to new methods for characterizing the "lacunarity" texture of an image, the September 2010 application claiming priority to a provisional patent applications filed a year earlier. Our September 4, 2008 patent filing concerns certain dermatology information associated with MelaFind® and claims priority to a provisional application filed a year earlier. The innovative aspects of the MelaFind® user interface are described in our patent filed November 1, 2010, and likewise claims priority to a provisional patent application filed a year earlier.

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, give us a competitive advantage; however, 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 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 Federal 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 (a set of current good manufacturing practice requirements put forth by the FDA which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation and servicing of finished

devices) ("QSR"). Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, as well as general controls. Some Class I and Class II devices are exempted by regulation from the premarket notification, or 510(k), clearance requirement or the requirement of compliance with certain provisions of the QSR. 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. The Company's PMA application has been submitted and found to be sufficiently complete by the FDA. The FDA has begun an in-depth review of the submitted information. During this review period, the FDA may request additional information, or clarification of information already provided. Also during the review period, the FDA convened an advisory panel of experts from outside the FDA to review and evaluate the application and provide recommendations to the FDA. In addition, the FDA generally will conduct pre-approval inspections of the manufacturing facilities to ensure compliance with the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures.

In October of 2004, we entered into a binding Protocol Agreement with the FDA, which is an agreement for the conduct of the pivotal trial in order to establish the safety and effectiveness of MelaFind®. In October 2006, we announced that the FDA had informed us that when submitted, the MelaFind® PMA application would receive expedited review.

On November 18, 2010, the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel. The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on the FDA. In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendment.

Upon obtaining pre-market approval from the FDA, we plan to launch MelaFind® commercially in the United States.

Notwithstanding the Protocol Agreement or the positive vote of the General and Plastic Surgery advisory Panel, the FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- MelaFind® may not be safe or effective to the FDA's satisfaction;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter which indicates the PMA has been approved, or an approvable letter, which usually contains a number of conditions which must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device for certain indications. If the FDA's

evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter.

The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed while the trials are conducted and the data acquired are submitted in an amendment to the PMA. Even with additional trials, the FDA may not approve the PMA application. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling and device specifications, materials or design of a device that is approved through the PMA process. 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. We have not been required to file an IDE application for the MelaFind® clinical studies because FDA has considered them to be "Non-Significant Risk" ("NSR") studies subject to abbreviated IDE regulations, which do not require formal IDE submission. 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 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. 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. Although we believe our clinical trial satisfies the FDA Protocol Agreement, the trial may ultimately be determined to be inadequate to support approval of a PMA application, or 510(k) clearance.

Delays in receipt of or failure to receive FDA approval, 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. Even if granted, the approvals may include significant limitations on the intended use and indications for use for which our products may be marketed.

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 removals 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.

Also, the FDA may require us to conduct post-market studies or order us to establish and maintain a system for tracking our products through the chain of distribution to the patient level. 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, including those applicable to the conduct of our clinical trials, can 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, specification developers, and some suppliers of components are also required to manufacture our products in compliance with current Good Manufacturing Practices ("cGMP") requirements set forth in the 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 will be subject to both FDA and Federal Trade Commission regulations. In addition, the sale and marketing of MelaFind® will be 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. The time required to obtain approval internationally varies as well and may be longer or shorter than that required for FDA approval. The approval time depends on the device classification and quality system requirements for that country. In order to distribute our product internationally we have initiated work towards launching MelaFind® in the European Union ("EU"), which includes 27 countries in Europe. We have also begun evaluation and planning for product distribution in Australia and Brazil.

In the EU, medical devices require a 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.

For CE marking, the device is classified into one of four classifications that are similar to FDA device classifications. MelaFind® is an "active", non-implantable Class IIa device requiring compliance with EU Council Directive 93/42/EEC. The device manufacturer is required to implement a Quality Management System ("QMS") and, in most cases, to comply with the applicable Medical Device Directive ("MDD") in accordance with the International Organization for Standardization's ISO 13485. The method of assessing conformity varies but normally involves a combination of self-assessment by the manufacturer and a third party assessment typically consisting of an audit of the manufacturer's quality system and an assessment by a "Notified Body" demonstrating the manufacturer's product compliance to the MDD. A Notified Body is an organization that has been accredited by a country to assess whether a product meets certain predetermined standards. A Technical File or Design Dossier (Class III) is prepared by the manufacturer providing detailed information for submission to the Notified Body. Devices that comply with the requirements of the MDD will be entitled to bear the CE conformity marking ("CE Mark"), indicating that the device conforms to the essential requirements of the applicable directive(s) and, accordingly, can be commercially distributed throughout Europe.

The Australian regulatory process for medical devices is similar to the EU regulatory process. In Australia, devices must comply with the Therapeutic Goods (Medical Devices) Regulations of 2002 or, if the device has a European CE Mark, the CE certificates can be used as "Manufacturer's Evidence" for compliance when submitted to the Therapeutic Goods Administration ("TGA"). If the device does not have a European CE Mark, the manufacturer is required to submit a Technical File or Design Dossier to TGA. To achieve the required QMS compliance, most manufacturers comply with the ISO 13485 standard.

The Brazilian regulatory process for medical devices is also similar to the EU regulatory process. Medical devices in Brazil are regulated by the Agência Nacional de Vigilância Sanitária ("ANVISA"). A Technical File is needed for registration with ANVISA. The Brazilian quality system requirements are very similar to U.S. FDA 21 CFR Part 820, Quality System Regulations.

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®. MelaFind® will require FDA approval prior to commercialization in the U.S. The clinical studies of MelaFind® are considered by the FDA as NSR. Consequently, the trials are conducted under the auspices of an abbreviated IDE. We therefore only maintain limited domestic clinical trial liability insurance, as required by certain clinical sites. We have obtained clinical trial liability insurance in certain European countries where required by statute or clinical site policy. Although we have general liability insurance that we believe is appropriate, and anticipate obtaining adequate product liability insurance before commercialization of MelaFind®, this insurance is and will be subject to deductibles and coverage limitations. Our anticipated product liability insurance may not be available to us in amounts and on acceptable terms, if at all, and, if available, the coverages 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, 2010, we had 42 full-time and 5 part-time employees, of whom 25 were engaged in research and development (including clinical and regulatory affairs), 5 in production (including document control and quality assurance) and 17 in marketing, sales and administrative activities. We believe that our relationship with our employees is good.

Other

Since we believed it to be in the best interests of the Company to change its name to better reflect the Company's focus on early melanoma detection, on April 30, 2010 we changed our name to MELA Sciences, Inc. 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 ("SEC"). Copies are also available, without charge, from MELA Sciences, Inc., 50 South Buckhout Street, Suite 1, Irvington, New York, 10533, Attention: Secretary.

Item 1A. *Risk Factors*

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

Risks Relating to Our Business

We currently do not have, and may never develop, any commercialized products.

We currently do not have any commercialized products or any significant source of revenue. We have invested substantially all of our time and resources over the last nine years in developing MelaFind®. MelaFind® may require additional development and clinical evaluation and it will require regulatory approval, significant marketing efforts and substantial additional investment before it can provide us with any revenue. Our efforts may not lead to commercially successful products for a number of reasons, including:

- we may not be able to obtain regulatory approvals for MelaFind®, or the approved indication may be narrower than we seek;
- MelaFind® may not prove to be safe and effective in clinical trials to the FDA's satisfaction;
- physicians may not receive any reimbursement from third-party payers, or the level of reimbursement may be insufficient to support widespread adoption of MelaFind®;
- we may experience delays in our continuing development program;

- any products that are approved may not be accepted in the marketplace by physicians or patients;
- we may not have adequate financial or other resources to complete the continued development or to commence the commercialization of MelaFind® and we will not have adequate financial or other resources to achieve significant commercialization of MelaFind®;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost; and
- rapid technological change may make our technology and products obsolete.

If we are unable to obtain regulatory approval for or successfully commercialize MelaFind®, we will be unable to generate revenue.

We have not received, and may never receive, FDA or international regulatory approval to market MelaFind®.

We do not have the necessary regulatory approvals to market MelaFind® in the U.S. or in any foreign market. We plan to launch MelaFind® in the U.S. when the PMA is approved by the FDA and in Europe once we achieve the required regulatory approval and CE marking. The PMA process requires us to prove the safety and effectiveness of MelaFind® to the FDA's satisfaction. This process is expensive and uncertain, and requires detailed and comprehensive scientific and human clinical data. FDA review may take years after the PMA application was filed. The FDA may never grant approval. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- MelaFind® may not be safe or effective to the FDA's satisfaction;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

No precedent has been established for FDA approval of a device such as MelaFind® to aid in determining the appropriateness of biopsies of suspicious pigmented skin lesions. While the Company believes that results from the MelaFind® pivotal trial support a favorable PMA review, the FDA may not consider the data gathered in the trial sufficient to support approval of a PMA. The FDA may determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or even years while the trials are conducted and the data acquired are submitted in an amendment to the PMA. The occurrence of unexpected findings in connection with any subsequent clinical trial that may be required by the FDA may prevent or delay obtaining PMA approval, and may adversely affect coverage or reimbursement determinations. The FDA may require additional trials following approval of MelaFind®. If we are unable to complete subsequent clinical trials necessary to successfully support the MelaFind® PMA application, our ability to commercialize MelaFind®, and our business, financial condition, and results of operations would be materially adversely affected, thereby threatening our ability to continue operations.

If MelaFind® receives FDA or international regulatory approval, it may be only for narrow indications.

Even if approved, MelaFind® may not be approved for the indications that are necessary or desirable for successful commercialization. Our preference is to eventually obtain a broad indication for use aiding in the evaluation of almost all pigmented melanomas (other than those on palms, soles of the feet, in or near the eye, and inaccessible areas such as the edge of the nose). The final MelaFind® lesion classifier may not be able to identify the maximum number of types of melanoma possible. The indications for use must specify those lesion types for which the classifier has not been trained. Approximately five percent of melanoma lesions may be amelanotic, meaning they are not pigmented. These lesions cannot be differentiated by MelaFind®, which will be restricted to pigmented lesions. Approximately ten percent of pigmented melanoma lesions are nodular, a type of melanoma that is often missed by dermatologists in early stages. If nodular melanoma lesions are not sufficiently well-represented in the MelaFind® training database, the classifier may not differentiate nodular melanomas from non-melanomas with sufficient sensitivity and specificity. If we restrict

the indications for use of MelaFind® to exclude certain melanoma lesion types, in addition to the other restrictions, then the size of the market for MelaFind® and the rate of acceptance of MelaFind® by dermatologists may be adversely affected.

If we wish to modify MelaFind® after receiving FDA approval, including changes in indications or other modifications that could affect safety and effectiveness, additional approvals could be required from the FDA. We may be required to submit extensive pre-clinical and clinical data, depending on the nature of the changes. Any request by the FDA for additional data, or any requirement by the FDA that we conduct additional clinical studies, could delay the commercialization of MelaFind® and require us to make substantial additional research, development and other expenditures. We may not obtain the necessary regulatory approvals to market MelaFind® in the U.S. or anywhere else. Any delay in, or failure to receive or maintain, approval for MelaFind® could prevent us from generating revenue or achieving profitability, and our business, financial condition, and results of operations would be materially adversely affected.

MelaFind® may not be commercially viable if we fail to obtain an adequate level of reimbursement by Medicare and other third party payers. The markets for MelaFind® may also be limited by the indications for which its use may be reimbursed.

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 suspicious 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.

The commercial success of MelaFind® in both domestic and international markets may significantly depend on whether third-party coverage and reimbursement are available for services involving MelaFind®. 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, even if MelaFind® or future products we develop are approved for commercial sale, 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 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 (formerly called carriers and fiscal intermediaries), 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®.

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.

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

We began operations in December 1989. At that time we provided research services, mostly to U.S. government agencies, on classified projects. We have financed our operations since 1999 primarily 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, 2010 was approximately $19.9 million, and as of December 31, 2010, we had an accumulated deficit of approximately $99.1 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind®. Upon receiving PMA approval for MelaFind® from the FDA, we expect to incur significant sales, marketing and manufacturing expenses which will require additional funding.

As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

We expect to 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.

We do not know of any product possessing the diagnostic assistance capabilities of MelaFind®. 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.; Biocompatibles International , Ltd.; Biomips Engineering, Scibase AB, Balter Medical, Michelson Diagnostics; Riester and others. 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. If our products are approved for marketing, we will potentially be subject to competition from major optical imaging companies, such as: Raytheon Corporation, General Electric Co.; Siemens AG; Bayer AG; Welch Allyn, Inc.; 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.

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, including molecular imaging in which tagged antibodies search for cancer cell antigens, and molecular and genetic screening tests.

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 of any of these new technologies could result in a technological breakthrough in the diagnosis and/or treatment of melanoma, which could render **MelaFind®** obsolete.

For any additional clinical trials required for MelaFind® by the FDA or with respect to clinical trials relating to the development of our core technology for other applications, we depend on clinical investigators and clinical sites and other third parties to manage the 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.

With respect to any additional clinical studies for MelaFind® which may be required by the FDA or with respect to clinical trials relating to the development of the Company's core technology for other applications, we 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 our clinical trials. We rely on: pathologists and pathology laboratories; a contract research organization to assist in monitoring, collection of data, and ensuring FDA Good Clinical Practices ("GCP") are observed at our sites; a consultant biostatistician; and other third parties to manage the trial 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 may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, or if the clinical sites fail to comply adequately with the clinical protocols, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for MelaFind® or other products developed from our core technology. Our agreements with clinical investigators and clinical sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials 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 may be extended, delayed or terminated, and we may

be unable to obtain regulatory approval for, or successfully commercialize, MelaFind® or other products developed from our core technology.

In addition to the foregoing, any additional clinical studies for MelaFind® which are required by the FDA and any clinical trials relating to the development of the Company's core technology for other applications may be delayed or halted, or be inadequate to support PMA approval, 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 manufacturing facilities, 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.

If MelaFind® is approved for reimbursement, we anticipate experiencing significant pressures on pricing.

Even if Medicare covers a device for certain uses, that does not mean that the level of reimbursement will be sufficient for commercial success. We expect to experience pricing pressures in connection with the commercialization of MelaFind® and our future products 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 commercialize MelaFind® and therefore, on our liquidity and our business, financial condition, and results of operations.

In some foreign markets pricing and profitability of medical devices are subject to government control. In the U.S., we expect that there will continue to be federal and state proposals for similar controls. Also, the recent legislation on managed healthcare in the US and legislation intended to control the cost of publicly funded healthcare programs could significantly influence the purchase of healthcare services and products, and may force us to reduce prices for MelaFind® or result in the exclusion of MelaFind® from reimbursement programs.

MelaFind® may never achieve market acceptance even if we obtain regulatory approvals.

To date, only those patients who were treated by physicians involved in our clinical trials have been evaluated using MelaFind®. Even if we obtain regulatory approval, patients with suspicious lesions and physicians evaluating suspicious lesions may not endorse MelaFind®. 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 utilize MelaFind® until there is long-term clinical evidence to convince them to alter their existing methods of diagnosing or evaluating suspicious lesions and there are recommendations from prominent physicians that MelaFind® is

effective. We cannot predict the speed at which physicians may adopt the use of MelaFind®. By limiting the capital cost of MelaFind® to the physician, we believe we will accelerate its adoption and usage. However, by charging on a per patient basis we will increase the initial capital burden on the Company. If MelaFind® receives the appropriate regulatory approvals but does not achieve an adequate level of acceptance by patients, physicians and healthcare payers, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of MelaFind® will depend on a number of factors, including:

- perceived effectiveness of MelaFind®;
- convenience of use;
- cost of use of MelaFind®;
- availability and adequacy of third-party coverage or reimbursement;
- approved indications and product labeling;
- 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.

The success of MelaFind® will depend upon the acceptance by dermatologists who perform skin examinations and treat skin disorders, including industry opinion leaders, 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 any such recommendations will be obtained. To date, the medical community outside the limited circle of certain dermatologists specializing in melanoma has had little exposure to us and MelaFind®. Because the medical community is often skeptical of new companies and new technologies, 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, or later the general practice, medical community will perceive a need for or accept MelaFind®. In particular, given the potentially fatal consequences of failing to detect melanoma at the early, curable stages, practitioners may remain reluctant to rely upon MelaFind® even after we receive approval from the FDA for marketing the product. Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind®. Insufficient market acceptance of MelaFind® would have a material adverse effect on our business, financial condition and results of operations.

We may be unable to complete the development and commence commercialization of MelaFind® or other products without additional funding and we will not be able to achieve significant commercialization without additional funding.

As of December 31, 2010 we had $30.5 million in cash and cash equivalents. Our operations have consumed substantial amounts of cash for each of the last nine years. We currently believe that our available cash and cash equivalents will be sufficient to fund our anticipated levels of operations for at least the next twelve months. However, our business or operations may change in a manner that would consume available resources more rapidly than we anticipate. We expect to continue to spend substantial amounts on research and development. We will need additional funds to fully commercialize the product, including development of a direct sales force and expansion of manufacturing capacity. We expect that our cash used by operations will increase significantly in each of the next several years, and should we encounter any material delays or impediments, we may need additional funds to complete the development of MelaFind® and commence commercialization, and achieve significant commercialization of MelaFind®. Any additional equity financing

may be dilutive to stockholders, or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

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

Additional financing may not be available to us when we need it, or it may not be available on favorable terms.

If we are unable to obtain adequate financing on a timely basis, we may be required to significantly curtail or cease one or more of our development and marketing programs. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise pursue on our own. We also may have to reduce marketing, customer support and other resources devoted to our products. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience ownership dilution, could experience declines in our share price and the terms of any new equity securities may have preferences over our common stock.

If we are unable to establish sales, marketing and distribution capabilities or enter into and maintain arrangements with third parties to sell, market and distribute MelaFind®, our business may be harmed.

We do not have a sales organization, and have no experience as a company in the marketing and distribution of devices such as MelaFind®. To achieve commercial success for MelaFind®, we must develop a sales and marketing force and enter into arrangements with others to market and sell our products. Following product approval, we currently plan to establish a small direct sales force to regionally market MelaFind® in the U.S. and/or Europe, focused on introducing it at high volume dermatologists' offices and training their staffs in its use, but we have not made any final determinations regarding the use of a particular marketing channel. We anticipate that we will need additional funds in order to fully implement this marketing plan. In addition to being expensive, developing such a sales force is time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. Qualified direct sales personnel with experience in the medical device market are in high demand, and there is no assurance that we will be able to hire or retain an effective direct sales team. Similarly, qualified, independent medical device representatives both within and outside the U.S. are in high demand, and we may not be able to build an effective network for the distribution of our product through such representatives. We have no assurance that we will be able to enter into contracts with representatives on terms acceptable or reasonable to us. Similarly, there is no assurance that we will be able to build an alternate distribution framework, should we attempt to do so.

We will need to contract with third parties in order to sell and install our products in larger markets, including non-specialist dermatologists. To the extent that we enter into arrangements with third parties to perform marketing and distribution services in the U.S. and Europe, our product revenue could be lower and our costs higher than if we directly marketed MelaFind®. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we will not be able to generate product revenue, and may not become profitable.

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing capabilities are insufficient to produce an adequate supply of MelaFind®, our growth could be limited and our business could be harmed.

We have no experience in manufacturing MelaFind® for commercial distribution. We currently have limited resources and facilities to commercially manufacture MelaFind®. In order to produce MelaFind® in the quantities we anticipate to meet market demand, we will need to increase our third-party manufacturing capacity. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, material procurement, problems with production yields, and quality control and assurance. Developing commercial-scale manufacturing facilities that meet FDA requirements would require the investment of substantial additional funds and the hiring and retaining of additional management and technical personnel who have the necessary manufacturing experience.

We currently outsource production to contract manufacturers. Any difficulties in the ability of third-party manufacturers to supply devices of the quality, at the times, and in the quantities we need, could have a material adverse effect on our business, financial condition, and results of operations. Similarly, when we enter into contracts for the third-party manufacture of our devices, any revenue received 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, or will be willing to do so at prices that allow MelaFind® to compete successfully in the market.

Upon MelaFind® receiving regulatory approval, if we are unable to manufacture or obtain a sufficient supply of product, maintain control over expenses, or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand, and our business will suffer. Additionally, upon MelaFind® receiving regulatory approval and we then need to make manufacturing changes, we may need to obtain additional approval for these changes.

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. Any of these conditions could have a material adverse impact on our business, financial condition and results of operations. 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.

Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business. We anticipate contracting for final device assembly and integration, but no contract for such services on a commercial basis has yet been procured.

Our manufacturing efforts currently rely on several vendors for critical materials such as: ON Semiconductor; Carl Zeiss Jena GmbH ("Zeiss") for lens and lens objective assemblies, A/B Electronics, AAEON, AmeriCad, Canvys Electronics, Sandisk and others to provide services or components of our devices. We are working with ASKION in Germany, which specializes in precision optics for the provision of the hand-held imaging devices. In addition, we are utilizing Nexcore Technology Inc., an FDA good manufacturing practices ("GMP") compliant and certified ISO13485 and ISO9001 original equipment 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 manufacturers 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 not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- 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.

Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

We have entered into an agreement with ASKION to continue developmental engineering, production and testing of our hand-held imaging device. Failure to maintain such an agreement with ASKION on mutually acceptable terms would require us to expand our own manufacturing facilities or obtain such services elsewhere. Similarly, through ASKION we have entered into a production agreement with Zeiss for lenses and lens objective assemblies. The manufacturing agreement with ASKION includes the integration of the Zeiss lenses in the hand-held imaging devices. Our planned reliance upon an outside provider for assembly and production services subjects us to the risk of adverse consequences from delays and defects caused by the failure of such outside supplier to meet its contractual obligations, including confidentiality obligations in the case of Zeiss, which is an affiliate of Carl Zeiss AG, a potential competitor. The failure by us or our supplier to produce a sufficient number of hand-held imaging devices that can operate according to our specifications could delay the commercial sale of MelaFind®, and would adversely affect both our ability to successfully commercialize MelaFind® and our business, financial condition and results of operations.

We may be required to purchase obsolete parts for MelaFind®:

Our MelaFind® design incorporates certain unique components which may, from time-to-time, become obsolete. In an instance where replacing those components would potentially require an extensive re-design and re-approval process, we may have to make a significant 'last-time-buy' to provide component availability during that re-design and regulatory approval process, or our ability to produce MelaFind® may become impaired.

We will not be able to sell MelaFind® unless and until its design is verified and validated in accordance with current good manufacturing practices as set forth in the U.S. medical device Quality System Regulation ("QSR").

We are in the process, but have not yet successfully completed, all the steps necessary to verify and validate the design of the MelaFind® system that are required to be performed prior to commercialization. If we are delayed or unable to complete verification and validation successfully, we will not be able to sell MelaFind®, and we will not be able to meet our plans for the 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, 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.

Upon MelaFind® approval by regulatory authorities, 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. In particular, we and our suppliers are required to comply with the QSR and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, promotion, distribution, and shipping of MelaFind®, and with record keeping practices. We also will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports and registration and listing requirements. To the extent that we contract with third parties to manufacture some of our products, our 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 before approval for marketing. The FDA enforces the QSR and other regulatory requirements through unannounced inspections.

If we are found to be deficient in cGMP or QSR, we could be subject to FDA action of a type described below, which could negatively affect our ability to commercialize MelaFind®. There can be no assurance that the future interpretations of legal requirements made by the FDA or other 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 and other 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;
- delays in approving or refusal to approve MelaFind®;
- 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.

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. Additionally, healthcare is heavily regulated by the federal government, and by state and local governments. The federal laws and regulations affecting healthcare change constantly, thereby increasing the uncertainty and risk associated with any healthcare related venture, including our business and MelaFind®. 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 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"). All of the aforementioned are agencies within HHS. 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 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 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.

Healthcare policy changes, including recent legislation reforming the U.S. healthcare system, may have a material adverse effect on us.

In response to increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products and could limit the acceptance and availability of our products. Moreover, as discussed below, recent federal legislation would impose new excise taxes on medical device transactions. The adoption of some or all of these proposals, including the recent federal legislation, could have a material adverse effect on our financial position and results of operations.

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. These taxes 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 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, clearing-houses, 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 will likely 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. Because patent applications may take years to issue, there also may be applications now pending of which we are unaware that may later result in issued patents that MelaFind® infringes. 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 also 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 also 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, and 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, that 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 would be delayed.

Our long-term success is dependent, in large part, on the design, development and commercialization of MelaFind® and other new products and services in the medical device industry. 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 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 MelaFind® or other 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®. MelaFind® will require PMA approval prior to commercialization in the U.S. The clinical studies of MelaFind® are considered by the FDA as "Non-Significant Risk". Consequently, the trials are conducted under the auspices of an abbreviated Investigational Device Exemption. We therefore only maintain limited domestic clinical trial liability insurance, as required by certain clinical sites. We have obtained clinical trial liability insurance in certain European countries where required by statute or clinical site policy. Although we have general liability insurance that we believe is appropriate, and anticipate obtaining adequate product liability insurance before commercialization of MelaFind®, this insurance is and will be subject to deductibles and coverage limitations. Our anticipated product liability insurance 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. 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 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 the withdrawal of, or inability to recruit, clinical trial volunteers, or 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 have become subject to claims in securities and shareholders actions which if determined adversely to the Company could have a material adverse impact on our business.

We and certain of our officers and directors are named as defendants in three purported securities class action lawsuits, each filed in the U.S. District Court for the Southern District of New York, and in a shareholder derivative lawsuit, filed in the Supreme Court of the State of New York. All of the purported securities class actions have since been consolidated into one securities class action. These lawsuits were brought on behalf of a putative class of purchasers of our securities from February 13, 2009 through November 16, 2010, and seek unspecified damages. We believe that we have meritorious defenses and we intend to vigorously defend against these lawsuits; however, as with any litigation, we cannot predict with certainty the eventual outcome of this litigation. Furthermore, we expect to incur expenses, some of which may not be covered by our insurance, in defending these lawsuits. An adverse outcome could have a material adverse effect on our business and our business could be materially harmed.

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 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 may use the internet as a medium to provide quality control calibration services to physicians. We also plan to 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.

We will be obligated to comply with Federal Communications Commission regulations for radio transmissions used by our products.

Versions of MelaFind® may rely on radio transmissions from the hand-held imaging device to a base station that may be connected to the internet. Applicable requirements will restrict us to a particular band of frequencies allocated to low power radio service for transmitting data in support of specific diagnostic or therapeutic functions. Failure to comply with all applicable restrictions on the use of such frequencies, or unforeseeable difficulties with the use of such frequencies, could impede our ability to commercialize MelaFind®.

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

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 manufacturing, 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. We may be 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.

Failure to obtain and maintain regulatory approval in foreign jurisdictions will prevent us from marketing abroad.

Outside the U.S., we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, in addition to other risks. Foreign regulatory bodies have established varying regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. We may not obtain foreign regulatory approvals on a timely basis, if at all. Foreign regulatory agencies, as well as the FDA, periodically inspect manufacturing facilities both in the U.S. and abroad. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We have initiated actions to obtain foreign regulatory approvals. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize MelaFind® in any market on a timely basis, or at all. Our inability or failure to comply with varying foreign regulation, or the imposition of new regulations, could restrict our sale of products internationally.

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

We are highly dependent on our senior management, especially Joseph V. Gulfo, M.D., our President and Chief Executive Officer and Dina Gutkowicz-Krusin, Ph.D., our Director of Clinical Research. Our success will depend on our ability to retain our current senior management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel.

Competition for senior management personnel, as well as scientists, clinicians, engineers, and experienced sales and marketing individuals, is intense, and we may not be able to retain our personnel. The loss of the

services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the development and introduction 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. Each of our officers may terminate their employment at any time without notice and without cause or good reason.

We expect to expand our operations and grow our research and development, product development and administrative operations. This expansion is expected to place a significant strain on our management, and will 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.

Our financial results for future periods will be affected by the attainment of milestones.

We have granted to certain employees stock options that vest with the attainment of various time-based or controllable performance milestones. During the attainment of these controllable milestones we recognize a stock based compensation expense in an amount based on the fair value of the options. We have also granted options that vest upon attainment of development milestones out of our control. Upon the attainment of each of these relevant development milestones, which include FDA approval of the MelaFind® PMA, there will be a significant compensation charge based on the fair value of such options.

Climate control policy changes, including regulations issued by the Environmental Protection Agency and negotiated international treaties, could have an impact on our Company.

We cannot predict whether climate control legislation will be enacted and treaties ratified, the final form any legislation or treaties might take, or the effects of such legislation or treaties. If climate control legislation and/or regulations are enacted or treaties ratified, our operations or the operations of our suppliers could be adversely impacted affecting our ability to successfully launch MelaFind® in the U.S. marketplace.

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

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

Risks Relating to our Common Stock

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

The Sarbanes-Oxley Act of 2002 ("SOX"), as well as rules subsequently 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 new 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. On each of June 30, 2008, 2009 and 2010, our market capitalization exceeded $75 million. As a result we had our independent registered public accounting firm attest to our compliance with Section 404 of SOX as of December 31, 2008, 2009 and 2010. 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, and our independent registered public accounting firm to attest to, our internal

controls, as required by Section 404 of the SOX. As a small company with limited capital and human resources, going forward 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.

An active public market for our common stock may not be sustained. Further, we cannot be certain that the market price of our common stock will not decline below the amount required by NASDAQ to maintain a listing on its Capital Market. Should we fail to meet the minimum standards established by NASDAQ for its Capital Market, we could be de-listed meaning shareholders might be subject to limited liquidity.

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. Between October 28, 2005 (the date of our initial public offering) and December 31, 2010, our stock price has ranged from $2.29 to $12.24 per share. 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:

- results of our research and development efforts and our clinical trials;
- the timing of regulatory approval for our products;
- failure of any of our products, if approved, to achieve commercial success;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the U.S. and foreign countries;
- 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 and third-party reimbursement in the US 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 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 20,000 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.

Item 3. ***Legal Proceedings***

On November 19, 2010, a purported securities class action complaint was filed in the U.S. District Court for the Southern District of New York, naming as defendants the Company and certain of its officers and directors, entitled *Randall J. Pederson, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman,* No. 7:10-cv-08774-JFM. Two similar complaints were also filed, one on December 2, 2010 and the other on January 20, 2011, in the same District Court, entitled *Amy Steigman, Individually and on Behalf of All Others Similarly Situated v. MELA*

Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman, No. 7:10-cv-09024-JFM; and *Martin Slove and Linda Slove, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman,* No. 1:11-cv-00429-JFM. These three securities class actions were consolidated into one action on February 15, 2011, entitled *In re MELA Sciences, Inc. Securities Litigation*, No. 10-Civ-8774-JFM ("securities class action"). The securities class action plaintiffs assert violations of the Securities Exchange Act of 1934, alleging, among other things, that defendants made misstatements and omissions regarding the Company's product, MelaFind®, on behalf of stockholders who purchased the Company's common stock during the period from February 13, 2009 through November 16, 2010, and seek unspecified damages.

On December 10, 2010, a shareholder of the Company filed a derivative lawsuit against certain of its officers and directors in the Supreme Court of the State of New York, entitled *Barry Jaffess v. Joseph V. Gulfo, Breaux Castleman, Sidney Braginsky, George C. Chryssis, Martin D. Cleary, Anne Egger, Charles Stiefel, Gerald Wagner, and Dan W. Lufkin*, Index No. 50026/2010. Based primarily on the same factual allegations in the securities class action, the complaint alleges that defendants breached their fiduciary duties. On February 24, 2011, the parties filed a stipulation of discontinuance of the derivative action and entered into a tolling agreement, which may allow the plaintiff to re-file the suit under certain circumstances.

The Company believes that it has meritorious defenses and intends to vigorously defend against these lawsuits; however, as with any litigation, we cannot predict with certainty the eventual outcome of this litigation. An adverse outcome could have a material adverse effect on our business and our business could be materially harmed.

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. ***Reserved***

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, 2009 through December 31, 2010 as reported by the NASDAQ Capital Market:

	High	Low
Year Ended December 31, 2010		
October 1 — December 31, 2010	$ 8.32	$2.51
July 1 — September 30, 2010	$ 7.50	$5.90
April 1 — June 30, 2010	$ 9.25	$5.51
January 1 — March 31, 2010	$12.24	$6.43
Year Ended December 31, 2009		
October 1 — December 31, 2009	$11.73	$7.85
July 1 — September 30, 2009	$10.95	$6.18
April 1 — June 30, 2009	$ 8.75	$4.35
January 1 — March 31, 2009	$ 7.50	$3.00

As of January 31, 2011, there were approximately 126 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 12/31/2010	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	2,132,879	$5.19	1,623,189
Equity compensation plans not approved by stockholders	—	—	—
Total	2,132,879	$5.19	1,623,189

Item 6. *Selected Financial Data*

The following table sets forth selected financial data. The financial information for the years ended December 31, 2008, 2009, and 2010 and as of December 31, 2009 and 2010 has been derived from our audited financial statements and related notes appearing in Part II Item 8 of this report and should be read together with such financial statements and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section appearing in Part II Item 7 of this report. The financial information for the years ended December 31, 2006 and 2007 and as of December 31, 2006, 2007, and 2008 have been derived from our audited financial statements not included in this report. The historical results are not necessarily indicative of results of any future periods.

	Year Ended December 31,				
	2006	2007	2008	2009	2010
	(In thousands, except share and per share data)				
Statements of Operations Data:					
Research and development expenses	$ 7,574	$ 7,678	$ 12,508	$ 10,950	$ 11,497
General and administrative expenses	4,526	5,400	5,766	7,631	8,738
Operating loss from continuing operations	(12,100)	(13,078)	(18,274)	(18,581)	(20,235)
Interest income	(728)	(1,054)	(468)	(45)	(32)
Other income, net	—	(59)	(201)	(83)	(280)
Loss from continuing operations	(11,372)	(11,965)	(17,605)	(18,453)	(19,923)
Gain from discontinued operations	781	28	—	—	—
Net loss	$ (10,591)	$ (11,937)	$ (17,605)	$ (18,453)	$ (19,923)
Net income (loss) per share, basic and diluted:					
Continuing operations	$ (1.01)	$ (0.84)	$ (1.08)	$ (.96)	$ (.83)
Discontinued operations	.07	—	—	—	—
Basic and diluted net loss per common share	$ (.94)	$ (.84)	$ (1.08)	$ (.96)	$ (.83)
Basic and diluted weighted average number of common shares outstanding	11,293,783	14,220,466	16,282,176	19,293,761	24,043,135

	As of December 31,				
	2006	2007	2008	2009	2010
			(In thousands)		
Balance Sheet Data:					
Total current assets	$ 21,771	$ 21,328	$ 15,836	$ 30,338	$ 31,044
Total assets	22,476	22,108	16,620	32,127	33,589
Total current liabilities	1,162	1,336	1,530	1,811	1,686
Total liabilities	1,162	1,336	1,530	1,811	1,790
Accumulated deficit	(31,225)	(43,162)	(60,767)	(79,220)	(99,143)
Total stockholders' equity	21,314	20,772	15,089	30,316	31,799

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, 2010 and the related notes appearing in Part II Item 8 of this report.

Overview

We are a medical device company focused on the design and development of a non-invasive, point-of-care instrument to aid in the detection of early melanoma. Our principal product, MelaFind®, features a hand-held imaging device that emits multiple wavelengths of light to capture images of suspicious pigmented skin lesions and extract data. We currently do not have any commercialized products or any source of revenue. All of our historical revenues have come from activities and products that have since been discontinued.

Unless otherwise indicated, the following discussion relates to our continuing operations.

The MelaFind® Pre-Market Approval ("PMA") application was submitted on June 9, 2009 and is under review at the U.S. Food and Drug Administration ("FDA"). A pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a Protocol Agreement. In addition, the MelaFind® PMA has been granted Expedited Review by the FDA.

On November 18, 2010, the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel. The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on the FDA. In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendment.

Upon obtaining approval from the FDA, we plan to launch MelaFind® commercially in the United States.

Also in 2010, the Company initiated steps toward being able to introduce the MelaFind® device commercially in Europe. The Company is actively planning representation, conducting market research activities and working with European regulatory agencies on achieving Conformite Europeenne ("CE") marking of MelaFind®.

Our revenue for the foreseeable future will depend on the approval of MelaFind® by the FDA and/or European regulatory agencies and the commercialization 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 based upon the results of the regulatory reviews.

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, 2010, we had an accumulated deficit of $99.1 million. We expect to continue to spend significant amounts on the PMA submission, FDA and European approval processes and, when approved, commercialization costs of MelaFind®.

We believe that our cash and cash equivalents on hand as of December 31, 2010 will be sufficient to fund our anticipated level of operations for at least the ensuing twelve months. We will however need to raise additional funds in order to achieve significant commercialization of MelaFind® and generate significant revenues.

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, 2010 were related primarily to the development of MelaFind® and review of the MelaFind® PMA by the FDA. We expect to continue to incur additional research and development expenses relating to MelaFind® prior to its commercial launch in the U.S. and selected markets outside the U.S. These additional expenses are subject to the risks and uncertainties associated with clinical trials and the FDA regulatory review and approval process. As a result, these additional expenses could exceed our estimated amounts, possibly materially, especially if the FDA requires additional clinical trials to support approval of MelaFind®.

General and administrative expenses consist primarily of salaries and related human resources expenses, legal expenses, including litigation expenses and general corporate activities and costs associated with our efforts toward development of a commercial infrastructure to market and sell MelaFind®. We expect selling, general and administrative expenses to increase as we build our sales force and marketing capabilities to support placing MelaFind® in the U.S. and selected markets outside the U.S.

At December 31, 2010, we had available income tax benefit from net operating loss carryforwards for federal income tax reporting purposes of approximately $39 million. The net operating loss carryforwards may be available to offset future taxable income expiring at various dates through the year 2030. The Company's ability to utilize its net operating losses may be significantly limited due to 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 1 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 accrued expenses are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

The Company has not received FDA or other regulatory approval for the sale of MelaFind® and has had no revenues from products since 2005 when it discontinued its DIFOTI operations.

Stock-Based Compensation

We account for non-employee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments issued in accordance with FASB ASC 505-50, "Equity Based Payments to Non-Employees."

We record compensation expense associated with stock options and other forms of equity compensation in accordance with FASB ASC 718, *Compensation-Stock Compensation*, as interpreted by SEC Staff Accounting Bulletins No. 107 and No. 110. A compensation charge is recorded, when it is probable that performance conditions will be satisfied, over the period estimated to satisfy the performance condition. The probability of vesting is updated at each reporting period and compensation is adjusted prospectively.

We have also granted to certain employees stock options that vest with the attainment of performance milestones over which we have no control of the timing required to satisfy. Upon the attainment of these performance milestones, there will be a significant compensation charge based on the fair value of such options on the date granted.

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 incurred 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 over estimate 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.

Results of Operations (in thousands)

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

Research and Development Expense

Research and development expense increased by $547 to $11,497 for the year ended December 31, 2010 from $10,950 for the year ended December 31, 2009. This was primarily attributable to increased costs at ASKION of $300 in R&D labor and $456 in product improvements offset by a $192 reduction of our clinical trial costs following completion of the pivotal trial related activities.

General and Administrative Expense

General and administrative expense increased by $1,107 to $8,738 for the year ended December 31, 2010 from $7,631 for the year ending December 31, 2009. Significant to this overall G&A increase were increases of $293 in outsourced professional costs, $182 in supplies and other costs, $169 in facility costs, $130 in travel and conferences, and $333 in non-cash items including depreciation/amortization of $236 and share-based compensation of $97.

Interest (Income)/Expense

Interest income for the year ended December 31, 2010 was $32 compared to $45 for the year ended December 31, 2009. The decrease reflected significantly lower interest rates available in 2010.

Other Income, net

Other income for the year ended December 31, 2010 increased from the comparable period in 2009 by $197. In 2010 the Company received a R&D grant from the federal government for $245 offset by a reduction in other income from the L'Oreal Feasibility Study and provision of KaVo transitional services both of which concluded in 2009.

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 commercial re-launch. As KaVo has not re-launched DIFOTI as of 2010 year end, the Company earned the minimum annual royalty of $20 in both 2010 and 2009. There was a gain of $9 on the disposal of fixed assets in 2010.

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Research and Development Expense

Research and development expense decreased by $1,558 to $10,950 for the year ended December 31, 2009 from $12,508 for the year ended December 31, 2008. This decrease was primarily attributable to a $1,952 reduction of our clinical trial costs following completion of the pivotal trial and a $779 reduction in our development costs as the MelaFind® design was finalized. Offsetting these decreases was increased spending of $946 in quality/regulatory associated with the PMA submission and FDA review process.

General and Administrative Expense

General and administrative expense increased by $1,865 to $7,631 for the year ended December 31, 2009 from $5,766 for the year ending December 31, 2008. This was principally attributable to an increase of $1,365 in marketing costs. The majority of this marketing increase took place in the last quarter of 2009, and included the production of promotional materials being readied for the projected launch of MelaFind® following FDA approval. Administrative costs increased by $500 from the 2008 level, including compensation costs of $292, recruiting of $120, and temporary help of $30 as the Company increased its personnel capabilities preparing for commercialization.

Interest (Income)/Expense

Interest income for the year ended December 31, 2009 was $45 compared to $468 for the year ended December 31, 2008. The decrease reflected significantly lower interest rates available in 2009.

Other Income, net

Other income for the year ended December 31, 2009 decreased from the comparable period in 2008 by $118.

Income earned under our joint research contract with L'Oreal was $91 below the 2008 level as the feasibility study was completed during the first quarter of 2009.

Earnings from the provision of DIFOTI transitional services in accordance with the terms of our DIFOTI sale and license agreement with KaVo decreased by $26 in 2009 compared to 2008 as the services were only provided in the first half of 2009. 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 commercial re-launch. The Company began earning the contractual minimum royalty in the second half of 2008. As KaVo has not re-launched DIFOTI as of year end 2009, the Company had royalty income of $20 in 2009 and $10 in 2008.

Loss on the abandonment/disposal of fixed assets was $20 in 2009. In connection with the Company's move to a new facility and the termination of existing leases at year end 2009, leasehold improvements with a net book value of $14 were abandoned and other fixed assets were disposed of during 2009 at an additional loss of $6.

Liquidity and Capital Resources (in thousands)

From inception, we have financed our operations primarily through the use of working capital from the sale of equity securities. To date, we have not borrowed (other than by issuing convertible notes, all of which have been converted into equity) or financed our operations through equipment leases, financing loans or other debt instruments. As of December 31, 2010, we had $30,521 in cash and cash equivalents as compared to $29,673 at December 31, 2009. The $848 increase in 2010 from 2009 reflects the $20,702 of net cash provided by 2010 financing activities offset by $18,820 of net cash used in operating activities and $1,034 of net cash used in investing activities. Our cash and cash equivalents at December 31, 2010 are liquid investments in cash with two commercial banks and money market accounts held in accounts that substantially exceed FDIC limits.

On October 28, 2005, we completed an initial public offering. We issued 4,000,000 shares of common stock on October 28, 2005 and 262,300 shares of common stock on November 15, 2005, both issuances at $5.00 per share. After deducting underwriting discounts and expenses and offering related expenses, the initial public offering resulted in net proceeds to the Company of approximately $17.7 million. On October 31, 2006 we entered into securities purchase agreements and a registration rights agreement with certain accredited investors for the private placement of 2,312,384 shares of the Company's common stock and warrants to purchase up to 346,857 shares of the Company's common stock for aggregate gross proceeds of approximately $13.2 million and net proceeds of approximately $12.5 million. The transaction closed November 3, 2006.

On July 31, 2007, the Company entered into a securities purchase agreement and registration rights agreement with certain accredited investors for the private placement of 2,000,178 shares of the Company's common stock and warrants to purchase up to 500,041 shares of the Company's common stock for aggregate gross proceeds of approximately $11.5 million and net proceeds of approximately $10.7 million. This transaction closed on August 3, 2007.

In a transaction which closed August 8, 2008, the Company completed a registered direct offering of 2,088,451 shares of common stock for aggregate gross proceeds of $11.9 million ($11 million net proceeds to the Company). Also, the Company completed a registered direct offering of 2,400,000 shares of common stock for aggregate gross proceeds of $15 million ($13.70 million net proceeds to the Company) which closed July 22, 2009.

On May 7, 2009, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited, pursuant to which Kingsbridge committed to purchase from time to time at the Company's sole discretion, up to the lesser of $45 million or 3,327,000 shares of the Company's common stock, prior to May 7, 2012 subject to various conditions for individual sales, including dollar, timing, and trading volume limitations, a minimum market per share price, and other contractual and regulatory requirements. There is no assurance that the Company will satisfy all the various conditions for individual sales enabling it to use all of the CEFF. In connection with this CEFF, the Company issued a 5 year warrant, exercisable as of November 7, 2009, to Kingsbridge to purchase up to 200,000 shares of our common stock at an exercise price of $11.35 per share with a Black Scholes Fair Value of $678,000. The issuance of this warrant was deemed to be a cost of the offering.

Under the CEFF, during 2009, the Company sold 1,824,941 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately $9.24, for gross proceeds of approximately $16.9 million and during 2010, the Company sold 406,744 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately $9.22, for gross proceeds of approximately $3.75 million. A proportionate share of the CEFF originating expenses was allocated to each of these sales from deferred offering costs. Net of expenses, proceeds from these sales were approximately $16.8 million in 2009 and $3.727 million in 2010. As of December 31, 2010, there were 1,095,315 shares of common stock remaining available for sale under the CEFF for a maximum of approximately $24.4 million, exclusive of the 200,000 outstanding warrants held by Kingsbridge. As of December 31, 2010, legal, accounting, and other costs associated with this agreement approximating $62,000 have been deferred and will be charged to equity as a reduction of proceeds from the CEFF or operations should management decide to abandon the CEFF.

In May 2010, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed $75 million. The registration statement was declared effective by the SEC on June 1, 2010 (File No. 333-167113). On June 30, 2010, the Company entered into an underwriting agreement, relating to the public offering of 2,200,000 shares of the Company's common stock, at a price to the public of $7.50 per share less underwriting discounts and commissions. 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 June 30, 2010, in connection with a takedown from the Company's effective shelf registration statement. The gross proceeds to the Company from the sale of the Common Stock totaled $16.5 million. After deducting the underwriters' discounts and commissions and other offering expenses payable by the Company, net proceeds were approximately $15.2 million. This offering closed on July 6, 2010. Approximately $58.5 million remains available under the Company's 2010 shelf registration statement as of December 31, 2010.

Cash Flows from Operating Activities

Net cash used in operations was $18,820 for the year ended December 31, 2010. For the year ended December 31, 2009, the net cash used in operations was $17,303. 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.

Cash Flows from Investing Activities

Net cash used in our investing activities was $1,034 for the year ended December 31, 2010 principally relating to the purchase of fixed assets. For the year ended December 31, 2009 net cash provided by investing activities was $854 principally relating to the purchase of fixed assets offset by the sale of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $20,702 for the year ended December 31, 2010 and reflects the net proceeds received from our financing arrangement with Kingsbridge Capital, net proceeds from our July 6, 2010 public offering of common stock and proceeds from the exercise of common stock options and warrants. For the year ended December 31, 2009, the net cash flows provided by financing activities was $32,760, which included the net proceeds received from our financing arrangement with Kingsbridge Capital, net proceeds from our July 22, 2009 registered direct offering of common stock, and proceeds from the exercise of common stock options and warrants.

Operating Capital and Capital Expenditure Requirements

We face certain risks and uncertainties, which are present in many emerging medical device companies. At December 31, 2010, we had an accumulated deficit of $99.1 million. To date, we have not commercialized our principal product, MelaFind®. We anticipate that we will continue to incur net losses for the foreseeable future as we proceed with the MelaFind® PMA approval process, expand our corporate infrastructure, and prepare for the potential commercial launch of MelaFind®. We do not expect to generate significant product revenue until we successfully obtain PMA approval for and begin selling MelaFind®. In order to achieve significant commercialization of MelaFind, we will need to obtain additional funding. We believe that our current cash and cash equivalents and the interest we earn on these balances will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next twelve months, whether or not we achieve commercial launch of MelaFind®. However, 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 the lack of available capital as a result of the current global economic crisis. 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 of medical devices such as MelaFind®and operating our Company, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current regulatory review process. Our future funding requirements will depend on many factors, including, but not limited to:

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

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2010 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

Payments Due by Period:

	Contractual Obligations				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
	(Dollars in thousands)				
Operating Leases	$2,598	$382	$849	$911	$456
Total	$2,598	$382	$849	$911	$456

Our long-term obligations represent a non-cancelable operating lease for our laboratory, assembly, and office space. The lease on approximately 20,000 square feet of office space expires in December 2016.

Related Party Transactions (in thousands)

Consulting Agreement with Breaux Castleman

In June 2003, the Company entered into a consulting agreement with Breaux Castleman, the Chairman of the Company's Board of Directors, for consulting services related to the FDA approval of MelaFind® and the Company's business and financial strategy. Under this agreement, Mr. Castleman receives compensation for each month of services rendered. The Company made payments pursuant to this consulting agreement of $99 in 2008, $24 in 2009, and $24 in 2010. This consulting agreement is terminable by either party on 30 days' written notice.

Consulting Agreement with Marek Elbaum, Ph.D.

Effective June 1, 2007, the Company entered into a an amended consulting agreement with Marek Elbaum, PhD, the Company's former President and Chief Science and Technology Officer. In consideration of the services as Chief Scientist to be provided, Dr. Elbaum was paid a monthly fee of $9 through January 2009. Dr Elbaum's contract was completed in January 2009.

Consulting Agreement with Robert Friedman, M.D.

During June 2005, the Company retained the services of Robert Friedman, M.D., for an initial term of one year as a consultant and medical advisor to the Company's Board of Directors. In consideration for these services, Dr. Friedman will be paid at a rate of $5 per day. This consulting agreement is automatically renewed for successive one-year terms unless either party terminates the agreement at least 30 days prior to the expiration of the agreement. The amounts paid to Dr. Friedman amounted to $63 in 2008 and $43 in 2009. The Company did not incur any liability to Dr. Friedman in 2010.

Consulting Agreement with Gerald Wagner, Ph.D.

Effective April 1, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D., a member of the Company's Board of Directors and its former acting Chief Operating Officer. Under this amended consulting agreement, the Company agreed to pay Dr. Wagner the annual amount of $180 payable monthly over the term of the agreement. In addition, in connection with his ongoing engagement as a consultant, Dr. Wagner received a stock option grant of 50,000 shares of the Company's common stock which vested upon commencement of the pivotal trial for Melafind® in January 2007. In addition, on March 24, 2006, Dr. Wagner received another stock option grant of 49,500 shares of the Company's common stock which vested immediately.

With the start of the pivotal clinical trial in January 2007, Dr. Wagner transitioned out of his role as acting Chief Operating Officer and entered into an amended and restated consulting contract with the Company. Under the terms of the amended contract, Dr. Wagner is paid a monthly retainer of $2.5 and will be paid $2.5 for each additional consulting day. This amended agreement will end 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 $70 in 2008, $30 in 2009 and $30 in 2010.

Consulting Agreement with Anne Egger

In March 2009, the Company entered into a consulting agreement with Anne Egger for certain consulting services primarily focusing on physician advocacy. The agreement was for an initial term of three months, and has subsequently been extended to run through September 2011, and may be terminated by either party with 30 days notice. Under the terms of the agreement, Ms. Egger is entitled to receive a consulting fee of $1.6 per day. Ms. Egger was appointed to the Company's Board of Directors as of June 10, 2009. During the years ended December 31, 2009 and 2010, Ms. Egger was paid $71 and $60, respectively, under this agreement.

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

In January 2010, the FASB issued ASU 2010-6, an update that improves the requirements related to Fair Value Measurements and Disclosures Subtopic 820-10 of the FASB Accounting Standards Codification originally issued as FASB Statement 157. This update requires enhanced disclosures about transfers between Level 1 and Level 2 assets and the disaggregated activity in the roll forward for level 3 Fair Value measurements. Except for the detailed Level 3 roll-forward disclosures, these new disclosures are effective for fiscal years beginning after December 15, 2009 and for interim periods within those fiscal years. The requirement to provide detailed disclosures about purchases, sales, issuances, and settlements in the roll-forward activity for Level 3 Fair Value measurements is effective for interim and annual reporting periods beginning after December 31, 2010. The Company does not expect the adoption of ASU 2010-6 to have a material impact on the Company's financial statements.

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

Our exposure to market risk at December 31, 2010 is confined to our cash and cash equivalents. We invest in cash and money market accounts with commercial banks. We currently do not hedge interest rate exposure. While declines in interest rates do impact the amount of interest income that our cash and cash equivalents will earn, we do not believe that we have any material exposure to interest rate risk arising from our investments, due to the nature of our accounts.

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, 2009 and 2010, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2010. 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, 2009 and 2010, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), MELA Sciences, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 2, 2011 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
March 2, 2011

MELA SCIENCES, INC.

BALANCE SHEETS

	December 31, 2009	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 29,673,420	$ 30,520,812
Prepaid expenses and other current assets	664,962	523,672
Total Current Assets	30,338,382	31,044,484
Property and equipment, net	1,571,956	2,073,602
Patents and trademarks, net	83,008	71,108
Deferred financing costs	85,570	62,391
Other assets	48,000	337,705
Total Assets	$ 32,126,916	$ 33,589,290
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable (includes related parties of $6,921 as of December 31, 2009)	$ 1,187,201	$ 1,096,505
Accrued expenses	590,600	559,975
Other current liabilities	33,285	29,538
Total Current Liabilities	1,811,086	1,686,018
Long Term Liabilities:		
Deferred rent	—	104,304
Total Long Term Liabilities	—	104,304
Total Liabilities	1,811,086	1,790,322
COMMITMENTS, CONTINGENCIES AND LITIGATION (Note 4)		
Stockholders' Equity:		
Preferred stock — $0.10 par value; authorized 10,000,000 shares:		
Issued and outstanding: none	—	—
Common stock — $0.001 par value; authorized 45,000,000 shares:		
Issued and outstanding 22,354,317 and 25,262,538 shares at December 31, 2009 and 2010, respectively	22,354	25,263
Additional paid-in capital	109,513,582	130,916,326
Accumulated deficit	(79,220,106)	(99,142,621)
Total Stockholders' Equity	30,315,830	31,798,968
Total Liabilities and Stockholders' Equity	$ 32,126,916	$ 33,589,290

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.

STATEMENTS OF OPERATIONS

	Year Ended		
	December 31, 2008	December 31, 2009	December 31, 2010
Operating expenses:			
Research and development	$ 12,507,959	$ 10,950,114	$ 11,496,634
General and administrative	5,766,238	7,631,251	8,738,203
Operating loss	(18,274,197)	(18,581,365)	(20,234,837)
Interest income	(467,587)	(45,259)	(31,582)
Other income, net	(201,579)	(83,262)	(280,740)
	(669,166)	(128,521)	(312,322)
Net loss	$(17,605,031)	$(18,452,844)	$(19,922,515)
Basic and diluted net loss per common share	$ (1.08)	$ (.96)	$ (.83)
Basic and diluted weighted average number of common shares outstanding	16,282,176	19,293,761	24,043,135

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2008, 2009 and 2010

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount				
Balance at January 1, 2008	15,401,882	$15,402	$ 63,930,689	$(12,136)	$(43,162,231)	$ 20,771,724
Exercise of options	141,823	141	73,234			73,375
Exercise of warrants	2,342	2	10,584			10,586
Issuance of shares of common stock in connection with a public offering(net of expenses)	2,088,451	2,089	10,970,695			10,972,784
Share-based compensation expense			860,751			860,751
Other comprehensive income				5,268		5,268
Net loss					(17,605,031)	(17,605,031)
Comprehensive loss (sub-total)						(17,599,763)
Balance at December 31, 2008	17,634,498	$17,634	$ 75,845,953	$ (6,868)	$(60,767,262)	$ 15,089,457
Exercise of options	151,457	152	212,119			212,271
Exercise of warrants	324,290	324	2,174,775			2,175,099
Cashless exercise of warrants	19,131	19	(19)			—
Issuance of shares of common stock in connection with a public offering (net of expenses)	2,400,000	2,400	13,696,779			13,699,179
Issuance of shares of common stock in connection with a Committed Equity Financing Facility (CEFF) (net of expenses)	1,824,941	1,825	16,757,222			16,759,047
Share-based compensation expense			826,753			826,753
Other comprehensive income				6,868		6,868
Net loss					(18,452,844)	(18,452,844)
Comprehensive loss (sub-total)						(18,445,976)
Balance at December 31, 2009	22,354,317	$22,354	$109,513,582	—	$(79,220,106)	$ 30,315,830
Exercise of options	12,944	13	33,075			33,088
Cashless exercise of options	16,262	16	(16)			—
Exercise of warrants	239,723	240	1,691,394			1,691,634
Cashless exercise of warrants	32,548	33	(33)			—
Issuance of shares of common stock in connection with a public offering (net of expenses)	2,200,000	2,200	15,231,471			15,233,671
Issuance of shares of common stock in connection with a Committed Equity Financing Facility (CEFF) (net of expenses)	406,744	407	3,719,697			3,720,104
Share-based compensation expense			727,156			727,156
Net loss					(19,922,515)	(19,922,515)
Balance at December 31, 2010	25,262,538	$25,263	$130,916,326	—	$(99,142,621)	$ 31,798,968

The accompanying notes are an integral part of these financial statements

MELA SCIENCES, INC.

STATEMENTS OF CASH FLOWS

	Year Ended		
	December 31, 2008	December 31, 2009	December 31, 2010
Cash flows from operating activities:			
Net loss	$(17,605,031)	$(18,452,844)	$(19,922,515)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of fixed assets	—	—	(8,811)
Loss on disposal/abandonment of fixed assets		20,186	
Depreciation and amortization	308,977	314,352	552,860
Noncash compensation	860,751	826,753	727,156
Amortization of discount on marketable securities	519	—	—
Changes in operating assets and liabilities:			
Decrease (increase) in prepaid expenses and other current assets	35,942	(289,350)	141,290
Increase (decrease) in accounts payable and accrued expenses	223,924	311,179	(121,321)
Increase (decrease) in other current liabilities	8,662	5,819	(3,747)
Decrease (increase) in other assets	600	(2,724)	(289,705)
Increase in deferred rent			104,304
Decrease in deferred income	(38,861)	(36,085)	—
Net cash used in operating activities	(16,204,517)	(17,302,714)	(18,820,489)
Cash flows from investing activities:			
Purchases of property and equipment	(313,020)	(1,251,211)	(1,044,079)
Sale of marketable securities	1,334,142	397,380	—
Proceeds from disposal of fixed assets	—	—	10,284
Net cash provided by (used in) investing activities	1,021,122	(853,831)	(1,033,795)
Cash flows from financing activities:			
Net proceeds from private placements/public offering	10,972,784	13,699,179	15,233,671
Net proceeds from Committed Equity Financing Facility	—	16,673,477	3,743,283
Proceeds from exercise of stock options	73,375	212,271	33,088
Proceeds from exercise of stock warrants	10,586	2,175,099	1,691,634
Net cash provided by financing activities	11,056,745	32,760,026	20,701,676
Net (decrease) increase in cash and cash equivalents	(4,126,650)	14,603,481	847,392
Cash and cash equivalents at beginning of year	19,196,589	15,069,939	29,673,420
Cash and cash equivalents at end of year	$ 15,069,939	$ 29,673,420	$ 30,520,812
Supplemental Schedule of Noncash Investing and Financing Activities:			
Unrealized loss (gain) on marketable securities	$ (5,268)	$ (6,868)	$ —
Amortization of deferred financing costs	—	$ 103,953	$ 23,179

The accompanying notes are an integral part of these financial statements

1. Principal Business Activities and Summary of Significant Accounting Policies:

Organization and Business

MELA Sciences, Inc., a Delaware corporation (the Company), is focused on the development of a non-invasive, point-of-care instrument (MelaFind®) to aid in the detection of early melanoma. The MelaFind® Pre-Market Approval ("PMA") application was submitted on June 9, 2009 and is under review at the U.S. Food and Drug Administration ("FDA"). A pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a Protocol Agreement. In addition, the MelaFind® PMA has been granted expedited review by the FDA. The Company is actively working with the FDA during the review process.

On November 18, 2010 the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel. The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on the FDA. In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendment.

Upon obtaining approval from the FDA, we plan to launch MelaFind® commercially in the United States.

Also in 2010, the Company initiated steps toward being able to introduce the MelaFind® device commercially in Europe. The Company is actively planning representation , conducting market research activities and working with European regulatory agencies on achieving Conformite Europeenne ("CE") marking of MelaFind®.

To date, the Company has not generated any revenues from MelaFind®. All of our historical revenues have come from activities and products that have since been discontinued, including our DIFOTI product which we discontinued in 2005. Under an exclusive sale and licensing agreement with KaVo Dental GmbH ("KaVo") to further develop and commercialize DIFOTI, KaVo pays us an annual royalty based on the number of DIFOTI related systems sold per calendar year. The Company began earning the contractual minimum royalty in the second half of 2008 and earned the minimum annual royalty in 2009 and 2010 as KaVo had not re-launched the product as of December 31, 2010.

At December 31, 2010, the Company has an accumulated deficit of $99.1 million and anticipates that it will continue to incur net losses for the foreseeable future in the development and commercialization of the Melafind® device. From inception, the Company has financed operations primarily through the sale of convertible preferred stock and subsequently sold common stock as part of an initial public offering on October 28, 2005, private placements in November 2006 and August 2007, registered direct offerings which closed August 2008 and July 2009, an underwritten public offering in July 2010, and the committed equity financing facility ("CEFF") with Kingsbridge Capital Limited (refer to Note 6, "Stockholders' Equity," for further details). With the exception of the additional funds that will be needed in order to achieve significant commercialization of MelaFind®, the Company believes that its cash and cash equivalents on hand will permit the Company to fund its anticipated levels of operations for at least the next twelve months, whether or not we achieve commercial launch of MelaFind®. The Company faces certain risks and uncertainties which are present in many emerging medical device companies regarding future profitability, ability to obtain future capital, protection of patents and property rights, competition, rapid technological change, government regulations, changing health care marketplace, recruiting and retaining key personnel, and third party manufacturing organizations.

Business Segments

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

Cash and Cash Equivalents

The Company's cash is held in nationally-chartered banks and the amounts the Company currently maintains with these banks exceeds the current federal insurance limits provided by the Federal Deposit Insurance Company. The Company has not experienced any loss of its cash or interest income. Cash equivalents are highly liquid debt instruments with an original maturity of three months or less at the date of acquisition. The carrying value of these instruments approximates fair value.

Property and Equipment

Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the lesser of the assets' useful lives or the remaining term of the lease.

Patents

Patents are carried at cost less accumulated amortization which is calculated on a straight-line basis over a period of 15 years.

Revenue Recognition

The Company has not received approval from the FDA nor any regulatory body outside of the U.S. for the sale of MelaFind® and has had no revenues from products other than from the sale of DIFOTI products which were discontinued in 2005.

Income Taxes

The Company accounts for income taxes using the asset and liability method of accounting 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's reassessment of its tax positions did not have a material impact on its results of operations and financial position.

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires the use of estimates and assumptions by management that affect reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to stock-based compensation arrangements and accrued expenses. Actual results could differ from these estimates.

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.

Research and Development

Research and development costs are expensed as incurred.

Stock-Based Compensation

The Company records compensation expense associated with stock options and other forms of equity compensation.

The Company grants to certain employees stock options that vest over a requisite service period or with the attainment of performance milestones over which the Company has control of the timing required to satisfy. A compensation charge is recorded over the service period or the probable period estimated to satisfy the performance condition. The probability of vesting is updated at each reporting period and compensation is adjusted prospectively.

The Company also grants to certain employees stock options that vest with the attainment of performance milestones over which the Company has no control of the timing required to satisfy. Upon the attainment of these performance milestones, there will be a significant compensation charge based on the fair value of such options on the date granted.

The Company accounts for non-employee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments issued.

With equity instruments that are not immediately vested compensation cost is measured on the date such instruments vest or a performance commitment is reached. Under this method of accounting, the Company estimates the total amount of deferred compensation when the grant is issued for the entire option value based on the Black-Scholes valuation model. Subsequently, the deferred compensation is adjusted each reporting period until vesting occurs and the charge is taken. Compensation attributable to non-vested options is not recorded until vesting occurs (see Note 7).

Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents and accounts payable. The Company believes the financial instruments' recorded values approximate current values because of their nature and respective durations.

Net Loss per Common Share

Basic net loss per 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 earnings (loss) per 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 basic net loss per common share since all potentially dilutive securities are anti-dilutive for each of the periods presented.

Potential common stock equivalents excluded consist of stock options and warrants which are summarized as follows:

	Year Ended December 31,		
	2008	2009	2010
Common stock options	2,069,080	2,031,023	2,132,879
Warrants	1,124,544	929,629	546,781
Total	3,193,624	2,960,652	2,679,660

Comprehensive loss

Comprehensive loss includes net loss and unrealized gains and losses on available-for-sale marketable securities. Cumulative unrealized gains and losses on available-for-sale marketable securities, if any, are reflected as accumulated other comprehensive loss in stockholders' equity on the Company's balance sheet. For the year ended December 31, 2008, comprehensive loss was $17,600 which includes a net loss of $17,605 and an unrealized gain on available-for-sale marketable securities of $5. For the year ended December 31, 2009, comprehensive loss was $18,446 which includes a net loss of $18,453 and an unrealized gain on available-for-sale marketable securities of $7, which offsets the unrealized loss of $7 at December 31, 2008. For the year ended December 31, 2010, comprehensive loss was equal to net loss as the Company did not hold any marketable securities in 2010.

Recently Adopted Accounting Pronouncements

In January 2010, the FASB issued ASU 2010-6, an update that improves the requirements related to Fair Value Measurements and Disclosures Subtopic 820-10 of the FASB Accounting Standards Codification originally issued as FASB Statement 157. This update requires enhanced disclosures about transfers between Level 1 and Level 2 assets and the disaggregated activity in the roll forward for level 3 Fair Value measurements. Except for the detailed Level 3 roll-forward disclosures, these new disclosures are effective for fiscal years beginning after December 15, 2009 and for interim periods within those fiscal years. The adoption of this standard did not have a material impact on the Company's financial statements. The requirement to provide detailed disclosures about purchases, sales, issuances, and settlements in the roll-forward activity for Level 3 Fair Value measurements is effective for interim and annual reporting periods beginning after December 31, 2010. The Company does not expect the adoption of ASU 2010-6 to have a material impact on the Company's financial statements.

2. Property and Equipment:

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

	December 31,		Estimated
	2009	2010	Useful Life
Leasehold improvements	$ 519	$ 786	Lease Term
Laboratory and research equipment	936	975	3-5 years
Office furniture and equipment	1,061	1,774	3-5 years
	2,516	3,535	
Accumulated depreciation and amortization	944	1,461	
	$1,572	$2,074	

Depreciation expense amounted to approximately $286, $302 and $541 for the years ended December 31, 2008, 2009 and 2010, respectively.

3. Patents:

Patents as shown in the accompanying balance sheets are net of accumulated amortization of $191 and $203 at December 31, 2009 and 2010, respectively. Amortization expense related to all patents was approximately $23, $12 and $12 for the years ended December 31, 2008, 2009 and 2010, respectively. Amortization expense of currently held patents is expected to amount to $12, $10, $4, $2 and $10 for the years ending December 31, 2011, 2012, 2013, 2014 and 2015, respectively.

4. Commitments, Contingencies and Litigation:

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:

2011	$ 382
2012	410
2013	439
2014	455
2015	456
2016	456
	$2,598

Rent expense charged to operations amounted to approximately $320, $332 and $416 for the years ended December 31, 2008, 2009, and 2010, respectively.

ASKION GmbH ("ASKION"), located in Gera Germany, which specializes in precision optics, has become an integral member of the MelaFind® development team and the Company expects to continue to work with ASKION for the foreseeable future. ASKION produced the MelaFind® hand-held imaging devices used in our pivotal clinical trials and is currently building additional units and performing other additional developmental activities.

Beginning in August 2006, the Company, primarily through ASKION, engaged Carl Zeiss Jena GmbH ("Zeiss") to build the lenses and assemblies, as well as provide certain technical consulting, for the MelaFind® units which have been used in the Company's pivotal clinical trials. This work was performed from 2006 through 2010 and is expected to continue on commercial MelaFind® units throughout 2011.

The Company has an employment agreement with its President and Chief Executive Officer ("CEO") which provides for a base salary, stock options, and discretionary performance bonuses. The agreement, which provides for automatic one year renewal terms, currently runs through the end of 2011.

On November 19, 2010, a purported securities class action complaint was filed in the U.S. District Court for the Southern District of New York, naming as defendants the Company and certain of its officers and directors, entitled entitled *Randall J. Pederson, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman,* No. 7:10-cv-08774-JFM. Two similar complaints were also filed, one on December 2, 2010 and the other on January 20, 2011, in the same District Court, entitled *Amy Steigman, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman,* No. 7:10-cv-09024-JFM; and *Martin Slove and Linda Slove, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman,* No. 1:11-cv-00429-JFM. These three securities class actions were consolidated into one action on February 15, 2011, entitled *In re MELA Sciences, Inc. Securities Litigation,* No. 10-Civ-8774-JFM ("securities class action"). The securities class

action plaintiffs assert violations of the Securities Exchange Act of 1934, alleging, among other things, that defendants made misstatements and omissions regarding the Company's product, MelaFind®, on behalf of stockholders who purchased the Company's common stock during the period from February 13, 2009 through November 16, 2010, and seek unspecified damages.

On December 10, 2010, a shareholder of the Company filed a derivative lawsuit against certain of its officers and directors in the Supreme Court of the State of New York, entitled *Barry Jaffess v. Joseph V. Gulfo, Breaux Castleman, Sidney Braginsky, George C. Chryssis, Martin D. Cleary, Anne Egger, Charles Stiefel, Gerald Wagner, and Dan W. Lufkin*, Index No. 50026/2010. Based primarily on the same factual allegations in the securities class action, the complaint alleges that defendants breached their fiduciary duties. On February 24, 2011, the parties filed a stipulation of discontinuance of the derivative action and entered into a tolling agreement, which may allow the plaintiff to re-file the suit under certain circumstances.

The Company expects to incur expenses in defending these lawsuits.

From time to time, the Company may be a party to certain legal proceedings, incidental to the normal course of business and the outcome of these legal proceedings cannot be predicted.

No provision has been made in the accompanying financial statements for any of the litigation matters described above.

5. Employee Benefit Plan:

The Company has a SIMPLE IRA defined contribution plan covering all qualified employees. An officer of the Company serves as trustee of the plan. The Company provides a matching contribution of up to 3% of each employee's salary. Company contributions to this plan amounted to approximately $72, $103 and $114 for the years ended December 31, 2008, 2009 and 2010, respectively.

6. Stockholders' Equity

On October 31, 2006, the Company entered into securities purchase agreements and a registration rights agreement with certain accredited investors for the private placement of 2,312,384 shares of the Company's common stock and warrants to purchase up to 346,857 shares of the Company's common stock for aggregate gross proceeds of approximately $13.2 million and net proceeds of approximately $12.5 million. Pursuant to the securities purchase agreements, for a purchase price of $5.70 each investor received one share of the Company's common stock and a warrant to purchase 0.15 of a share of the Company's common stock. The warrants are five-year warrants with an exercise price of $6.70 per share.

On July 31, 2007, the Company entered into a securities purchase agreement and a registration rights agreement with certain accredited investors for the private placement of 2,000,178 shares of the Company's common stock and warrants to purchase up to 500,041 shares of the Company's common stock for aggregate gross proceeds of approximately $11.5 million and net proceeds of approximately $10.7 million. The private placement closed August 3, 2007. Pursuant to the securities purchase agreement, for a purchase price of $5.75 each investor received one share of the Company's common stock and a warrant to purchase 0.25 of a share of common stock. The warrants are five-year warrants with an exercise price of $8.00 per share.

Pursuant to the terms of the registration rights agreements, the Company filed resale registration statements covering the shares in both private placements, including the shares issuable upon exercise of the warrants, with the SEC. In the unlikely event that the Company fails to meet certain obligations, as described in the registration rights agreements, the holders would be entitled to certain monetary damages.

However, in no event is the Company obligated to make payments in excess of 10% of the aggregate purchase price of the common shares. The Company has concluded that it is unlikely that the Company would be required to remit any payments to its investors for failing to maintain its effectiveness. The Company's

resale registration statements on Form S-3 were declared effective by the Securities and Exchange Commission on February 12, 2007 and September 11, 2007, respectively.

On June 26, 2008, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed $40 million. The SEC declared the registration statement effective on July 7, 2008. Management utilized this shelf registration statement to raise additional equity capital by completing a registered direct offering of 2,088,451 shares of the Company's common stock for aggregate gross proceeds of $11.9 million ($11 million approximate net proceeds to the Company) at a per share offering price of $5.68. The offering closed on August 8, 2008.

In addition, management utilized this shelf registration statement to raise additional equity capital by completing a registered direct offering of 2,400,000 shares of the Company's common stock for aggregate gross proceeds of $15 million ($13.7 million approximate net proceeds to the Company) at a per share offering price of $6.25. The offering closed on July 22, 2009. Approximately $13.1 million remains available under the Company's shelf registration statement as of December 31, 2010.

On May 7, 2009, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited, pursuant to which Kingsbridge committed to purchase from time to time at the Company's sole discretion, up to the lesser of $45 million or 3,327,000 shares of the Company's common stock, prior to May 7, 2012 subject to various conditions for individual sales, including dollar, timing, and trading volume limitations, a minimum market per share price, and other contractual and regulatory requirements. There is no assurance that the Company will satisfy all the various conditions for individual sales enabling it to use all of the CEFF. In connection with this CEFF, the Company issued a 5 year warrant, exercisable as of November 7, 2009, to Kingsbridge to purchase up to 200,000 shares of the Company's common stock at an exercise price of $11.35 per share with a Black Scholes Fair Value of $678. The issuance of this warrant was deemed to be a cost of the offering.

Under the CEFF, during 2009, the Company sold 1,824,941 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately $9.24, for gross proceeds of approximately $16.9 million and during 2010, the Company sold 406,744 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately $9.22, for gross proceeds of approximately $3.75 million. A proportionate share of the CEFF originating expense was allocated to each of these sales from deferred offering costs. Net of expenses, proceeds from these sales were approximately $16.8 million in 2009 and $3.727 million in 2010. As of December 31, 2010, there were 1,095,315 shares of common stock remaining available for sale under the CEFF for a maximum of approximately $24.4 million, exclusive of the 200,000 outstanding warrants held by Kingsbridge. As of December 31, 2010, legal, accounting, and other costs associated with this agreement approximating $62 have been deferred and will be charged to equity as a reduction of proceeds from the CEFF or operations should management decide to abandon the CEFF.

In May 2010, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed $75 million. The registration statement was declared effective by the SEC on June 1, 2010. On June 30, 2010, the Company entered into an underwriting agreement, relating to the public offering of 2,200,000 shares of the Company's common stock, at a price to the public of $7.50 per share less underwriting discounts and commissions. 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 SEC on June 30, 2010, in connection with a takedown from the Company's effective shelf registration statement. The gross proceeds to the Company from the sale of the common stock totaled $16.5 million. After deducting the underwriters' discounts and commissions and other offering expenses payable by the Company, net proceeds were approximately $15.2 million. This offering closed on July 6,

2010. Approximately $58.5 million remains available under the Company's 2010 shelf registration statement as of December 31, 2010.

The Company will require additional funds to achieve significant commercialization of MelaFind®.

As of December 31, 2010, the Company had 10,000,000 shares of $0.10 par value preferred stock authorized and no shares issued and outstanding.

7. Stock-Based Compensation and Warrants:

Stock Options

The Company has one stock option plan under which the board of directors may currently grant incentives to employees, directors, consultants and collaborating scientists in the form of incentive stock options, nonqualified stock options and restricted stock awards. The Company also has two other stock-based compensation plans pursuant to which stock options are outstanding but no new grants may be made.

Stock awards under the Company's stock option plans have been granted at prices which are no less than the market value of the stock on the date of the grant. Options granted under the 2005 Stock Incentive Plan (2005 Plan), are generally time-based or performance-based options and vesting varies accordingly. Options under this plan expire up to a maximum of ten years from the date of grant. Since the Company adopted the 2005 Plan, awards may not be granted under the Company's previous stock option plans.

On October 10, 2008, the formula based option, issued in 2004 to the Company's President and CEO from the Company's 2003 Stock Incentive Plan for 743,283 shares, at an exercise price of $0.46 a share, was cancelled. On October 10, 2008, the Company's President and CEO was granted stock options for 900,000 shares of the Company's common stock at an exercise price of $3.75 (the closing price on the grant date); 380,000 shares from the Company's 2005 Plan previously approved for issuance by the Compensation Committee of the Board of Directors and the stockholders of the Company, and 520,000 shares from the Company's 2005 Plan approved for issuance by the Compensation Committee of the Board of Directors subject to stockholder approval which was voted on and approved at the 2009 Annual Meeting of Stockholders.

Of the 900,000 common shares underlying these stock options granted to the Company's President and CEO, 180,000 shares vested immediately, 540,000 shares vest upon the Company receiving FDA approval of its PMA application for MelaFind®; and 180,000 shares vest in four equal annual installments commencing on the date of grant, the first anniversary of which was October 10, 2009. These 900,000 options expire ten years from the date of grant.

Compensation expense recognized in the Statement of Operations during 2008, 2009 and 2010 for stock options and restricted stock awards amounted to $861, $827 and $727, respectively. Cash received from options exercised under all share-based payment arrangements for the years ended December 31, 2008, 2009 and 2010 was $73, $212 and $33, respectively.

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

	For the Year Ended		
	December 31, 2008	December 31, 2009	December 31, 2010
Expected life	5 years	5-10 years	5-10 years
Expected volatility	60%	60-66%	60-67%
Risk-free interest rate	1.67 - 3.86%	1.69 - 2.67%	2.26 - 3.56%
Dividend yield	0	0	0

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. Starting with the three month period ending September 30, 2009, the expected volatility percentage is stated as calculated rather than as implied. The expected volatility assumptions were determined based upon the historical volatility of the Company's daily closing stock price. The calculated expected volatility approximates implied volatility from other publicly-traded stock that was established at the time of our IPO. The risk-free interest rate is based on the continuous 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, 2010, stock options to purchase 2,132,879 shares of common stock at exercise prices ranging from $1.00 to $11.11 per share are outstanding and are exercisable at various dates through 2020. The total number of options exercisable at December 31, 2008, 2009, and 2010 was 768,403, 893,585 and 942,916 respectively, with weighted average exercise prices of $4.30, $5.06 and $5.42, respectively. The aggregate intrinsic value of the options exercisable at December 31, 2010 is $115.

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

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2008	1,812,084	$2.96	3.5	
Granted	1,165,539	3.61	8.2	
Exercised	(141,823)	0.52		
Forfeited or expired	(766,720)	0.52		
Outstanding at December 31, 2008	2,069,080	4.39	5.8	
Granted	213,400	8.60	4.7	
Exercised	(151,457)	1.40		
Forfeited or expired	(100,000)	3.84		
Outstanding at December 31, 2009	2,031,023	5.09	5.2	
Granted	250,300	6.12	8.6	
Exercised	(29,206)	3.92		
Forfeited or expired	(119,238)	5.72		
Outstanding at December 31,2010	2,132,879	5.19	5.4	$115
Vested and exercisable at December 31, 2010	942,916	5.42	3.2	115

During the years ended December 31, 2008, 2009 and 2010 the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was $2.89, $4.82 and $4.26 respectively per share. The total intrinsic value of options exercised during the years ended December 31, 2008, 2009 and 2010 was $664, $1,106 and $87, respectively. The requisite service periods for options granted during 2008, 2009 and 2010 for employees and consultants were four to five years and for options granted to directors the requisite service periods were one year.

The following table summarizes information about stock options outstanding at December 31, 2010:

	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
$1.00	48,952	1.9 years	1.00	48,952	1.00
$1.01-$4.50	1,146,652	6.9 years	3.83	371,364	3.88
$4.51-$11.11	937,275	7.1 years	7.07	522,600	6.93
$1.00-$11.11	2,132,879	5.2 years	$5.19	942,916	$5.42

As of December 31, 2010, of the total 2,132,879 options outstanding 1,189,963 have not vested. Of this total unvested amount 908,813 will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. There was $3,439 of total unrecognized compensation cost related to unvested options, of which approximately $2,053 will be recognized upon PMA approval, $818 upon achievement of other milestones and $568 upon completion of the requisite service period.

Warrants

Issued	2005	2006	2007	2009	Total
Outstanding at December 31, 2009	143,125	173,963	412,541	200,000	929,629
Exercised	(32,548)	(173,963)	(65,760)		(272,271)
Forfeited	(87,452)				(87,452)
Expired	(23,125)				(23,125)
Outstanding at December 31, 2010	—	—	346,781	200,000	546,781

In connection with the Company's initial public offering in October 2005, the Company issued 150,000 warrants to the underwriters to purchase shares of the Company's common stock at $6.25 per share. These five-year warrants contained a cashless exercise provision which was utilized in issuance of 32,548 shares and forfeiture of 87,452 warrants.

As previously discussed in connection with the Company's private placement in October 2006, the Company issued warrants to purchase up to 346,857 shares of the Company's common stock at a price of $6.70 per share. According to the provisions of the warrant agreement, the Company called the outstanding balance of these warrants in 2010.

As previously discussed in connection with the Company's private placement in August 2007 the Company issued warrants to purchase up to 500,041 shares of the Company's common stock. At December 31, 2010, 346,781 of the 2007 warrants were outstanding. The warrants are exercisable for five years at a price of $8.00 per share.

In addition, in connection with the May 7, 2009 CEFF with Kingsbridge Capital, the Company issued a 5 year warrant, exercisable as of November 30, 2009, to Kingsbridge to purchase up to 200,000 shares of the Company's common stock at an exercise price of $11.35 per share. As of December 31, 2010, these warrants remain outstanding.

8. Related Party Agreements (see also Note 4):

The Company has in place the following consulting agreements with related parties.

Consulting Agreement with Breaux Castleman

In June 2003, the Company entered into a consulting agreement with Breaux Castleman, the Chairman of the Company's Board of Directors, for consulting services related to the FDA approval of MelaFind® and the Company's business and financial strategy. Under this agreement, Mr. Castleman receives compensation for each month of services rendered. The Company made payments pursuant to this consulting agreement of $99 in 2008, $24 in 2009, and $24 in 2010. This consulting agreement is terminable by either party on 30 days' written notice.

Consulting Agreement with Marek Elbaum, Ph.D.

Effective May 31, 2005, the Company entered into a new consulting agreement with Marek Elbaum, PhD, the Company's former President and Chief Science and Technology Officer. In consideration of the services as Chief Scientist, the Company agreed to pay Dr. Elbaum a monthly fee of $15. The term of this agreement extended for a period of two years and was automatically renewable for an additional one year period. Dr. Elbaum and the Company entered into an amended agreement effective June 1, 2007. Under the terms of the amended agreement, Dr. Elbaum was paid a monthly fee of $9 through January 2009. Dr Elbaum's contract was completed in January 2009.

Consulting Agreement with Robert Friedman, M.D.

During June 2005, the Company retained the services of Robert Friedman, M.D., for an initial term of one year as a consultant and medical advisor to the Company's Board of Directors. In consideration for these services, Dr. Friedman will be paid at a rate of $5 per day. This consulting agreement is automatically renewed for successive one-year terms unless either party terminates the agreement at least 30 days prior to the expiration of the agreement. The amounts paid to Dr. Friedman amounted to $63 in 2008 and $43 in 2009. The Company did not incur any liability to Dr. Friedman in 2010.

Consulting Agreement with Gerald Wagner, Ph.D.

Effective April 1, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D., a member of the Company's Board of Directors and its former acting Chief Operating Officer. Under this amended consulting agreement, the Company agreed to pay Dr. Wagner the annual amount of $180 payable monthly over the term of the agreement. In addition, in connection with his ongoing engagement as a consultant, Dr. Wagner received a stock option grant of 50,000 shares of the Company's common stock which vested upon commencement of the pivotal trial for Melafind® in January 2007. In addition, on March 24, 2006, Dr. Wagner received another stock option grant of 49,500 shares of the Company's common stock which vested immediately.

With the start of the pivotal clinical trial in January 2007, Dr. Wagner transitioned out of his role as acting Chief Operating Officer and entered into an amended and restated consulting contract with the Company. Under the terms of the amended contract, Dr. Wagner is paid a monthly retainer of $2.5 and will be paid $2.5 for each additional consulting day. This amended agreement will end 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 were $70 in 2008, $30 in 2009 and $30 in 2010.

Consulting Agreement with Anne Egger

In March 2009, the Company entered into a consulting agreement with Anne Egger for certain consulting services primarily focusing on physician advocacy. The agreement was for an initial term of three months, and has subsequently been extended to run through September 2011, and may be terminated by either party with

30 days notice. Under the terms of the agreement, Ms. Egger is entitled to receive a consulting fee of $1.6 per day. Ms. Egger was appointed to the Company's Board of Directors as of June 10, 2009. The Company made payments pursuant to this consulting agreement of $71 in 2009 and $60 in 2010.

9. Other Income (including gain on sale of discontinued operations):

During March 2007, the Company entered into an agreement with L'Oreal to study the feasibility of using the Company's novel multi-spectral imaging technology for the evaluation and differentiation of pigmented skin lesions of cosmetic importance. Pursuant to the agreement, L'Oreal was responsible for all costs and expenses incurred in connection with the Feasibility Program, and reimbursed MELA Sciences for expenses incurred by EOS with respect to the Feasibility Program. The Feasibility Program was concluded during 2009.

During the years ended December 31, 2008 and 2009, the Company earned $141 and $50 respectively, recorded as other income, to offset expenses incurred by MELA Sciences under the Feasibility Program with L'Oreal.

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. The Company began earning the contractual minimum royalty in the second half of 2008 and earned the minimum annual royalty in 2009 and 2010 as KaVo had not re-launched the product as of December 31, 2010.

10. Income Taxes:

The Company has incurred net losses since inception, accordingly, it has not provided for income taxes for the years ended December 31, 2008, 2009 and 2010.

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:

	Year Ended December 31,		
	2008	2009	2010
Computed expected tax benefit	$(5,986)	$(6,274)	$(6,774)
State tax benefit, net of federal effect	(1,056)	(1,107)	(1,195)
Increase in the valuation allowance	7,042	7,381	7,969
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, 2009 and 2010 are as follows:

	December 31, 2009	December 31, 2010
Deferred tax assets:		
Net operating loss carryforwards	$ 13,289	$ 16,681
Capitalized research and developmental costs	16,019	20,389
Non-cash compensation	1,682	1,889
Total deferred tax assets	30,990	38,959
Less valuation allowance	(30,990)	(38,959)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. 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, 2009 and 2010. The Company's valuation allowance against its deferred tax assets increased by $7,042, $7,381 and $7,969 for the years ended December 31, 2008, 2009 and 2010, respectively.

At December 31, 2010, the Company has net operating loss carryforwards of approximately $39 million 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 has conducted a study to determine the extent of the limitations. Based on the study, the Company believes that these limitations will not materially impact the Company's ability to utilize its net operating losses in the future. However, any future equity raise by the Company may limit the 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 adopted FASB ASC 740 on January 1, 2007. As a result of this implementation of ASC 740, the Company recognized no material adjustment in the liability for unrecognized income tax benefits. At the adoption date of January 1, 2007, the Company did 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 2006.

11. Quarterly Operating Results (Unaudited)

The following is a summary of operating results by quarter for the years ended December 31, 2010 and 2009:

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2010				
Net loss	$(5,051)	$(4,591)	$(4,955)	$(5,326)
Basic and diluted net loss per share of common stock	$ (0.22)	$ (0.20)	$ (0.20)	$ (0.21)
2009				
Net loss	$(3,990)	$(3,835)	$(5,048)	$(5,580)
Basic and diluted net loss per share of common stock	$ (0.23)	$ (0.22)	$ (0.26)	$ (0.25)

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 management, with the participation of our chief executive officer and our chief financial officer, has 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, 2010.

Based on such evaluation, our chief executive officer and our chief financial officer have concluded that, as of December 31, 2010, 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 our chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

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 the Committee of Sponsoring Organizations of the Treadway Commission 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, 2010.

EisnerAmper LLP, the independent registered public accounting firm, has issued their report on our internal control over financial reporting as of December 31, 2010. Their report is included in this Item 9A.

Report of Independent Registered Public Accounting Firm

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

We have audited MELA Sciences, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Report of Management on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions, and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company' s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, MELA Sciences, Inc., maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of MELA Sciences, Inc. as of December 31, 2009 and December 31, 2010, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2010, and our report dated March 2, 2011 expressed an unqualified opinion on those financial statements.

/s/ EisnerAmper LLP

New York, New York
March 2, 2011

Change in internal control over financial reporting

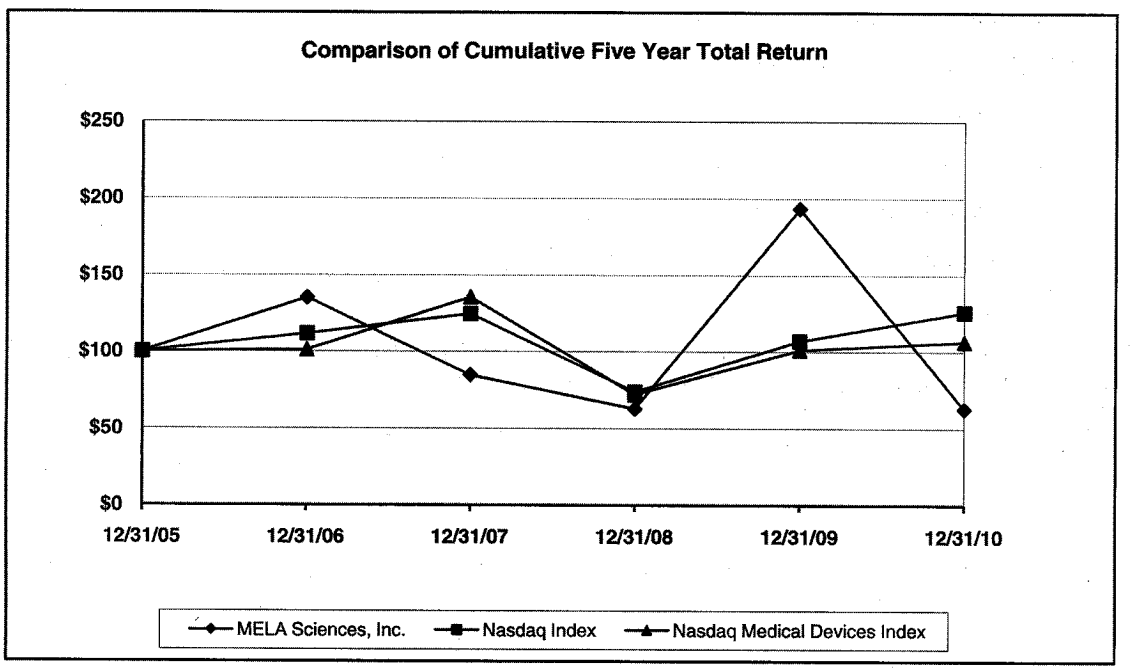
There were no changes in our internal control over financial reporting during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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.

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, 2010, 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	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Third Amended and Restated Bylaws of the Registrant.(2)
4.1	Specimen Stock Certificate.(2)
4.2	Second Amended and Restated Investor's Rights Agreement dated as of October 26, 2004 by and among the Registrant and the parties listed therein.(3)
4.3	Form of Warrant.(7)
4.4	Form of Warrant.(13)
4.5	Warrant dated May 7, 2009 issued by Electro-Optical Sciences, Inc. to Kingsbridge Capital Limited(16)
10.1*	Form of Indemnification Agreement for directors and executive officers.(2)
10.2*	1996 Stock Option Plan.(3)
10.3*	2003 Stock Incentive Plan, as amended.(3)
10.4*	2005 Stock Incentive Plan.(2)
10.5*	Employment Agreement dated as of January 5, 2004 between the Registrant and Joseph V. Gulfo.(3)
10.6	Consulting Agreement dated as of May 31, 2005 between the Registrant and Marek Elbaum.(3)
10.7*	Consulting Agreement dated as of June 20, 2003 between the Registrant and Breaux Castleman, as amended.(1)
10.8	Consulting Agreement dated as of June 1, 2005 between the Registrant and Robert Friedman, M.D.(1)
10.9	Production Agreement between the Registrant and ASKION GmbH dated as of January 25, 2006.(4)
10.10*	Amended and Restated Consulting Agreement effective as of April 1, 2006 between the Registrant and Gerald Wagner Consulting LLC.(10)
10.11*	Employment Offer Letter, dated April 24, 2006, between the Registrant and Richard I. Steinhart.(5)
10.12	Licensing Agreement between the Registrant and KaVo Dental GmbH, dated as of December 5, 2006.(9)
10.13*	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.(9)
10.14	Research and Feasibility Agreement between Registrant and L'Oreal S.A. dated as of March 26, 2007.(11)
10.15	Fifth Amendment dated as of August 24, 2007, by and between the Registrant and Bridge Street Commercial, LLC, for office space located at 1 Bridge Street, Irvington, New York.(12)
10.16	Common Stock Purchase Agreement dated as of May 27 between Electro-Optical Sciences, Inc. and Kingsbridge Capital Limited.(13)
10.17	Registration Rights Agreement dated as of May 7, 2009 between Electro-Optical Sciences, Inc. and Kingsbridge Capital Limited.(13)
10.18	Agreement of Lease, dated as of July 14, 2009, by and between Stanford Bridge LLC and Electro-Optical Sciences, Inc.(14)
10.19	Underwriter Agreement dated as of June 30, 2010 among MELA Sciences, Needham & Company, LLC and Leerink Swann LLC(15)
23.1#	Consent of EisnerAmper LLP
31.1#	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Indicates management compensatory plan, contract or arrangement

(1) Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on July 15, 2005.

(2) 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) Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on June 3, 2005.

(4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 31, 2006. Portions of this agreement have been omitted pursuant to a request for confidential treatment.

(5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 27, 2006.

(6) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on June 2, 2006.

(7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 1, 2006.

(8) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 11, 2006.

(9) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 31, 2007.

(10) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed on March 29, 2006.

(11) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on March 28, 2007.

(12) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2007.

(13) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on May 8, 2009.

(14) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 14, 2009.

(15) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on June 30, 2010

Filed herewith.

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/ Joseph V. Gulfo, M.D.
Joseph V. Gulfo, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: March 3, 2011

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/ Joseph V. Gulfo, M.D. **Joseph V. Gulfo, M.D.**	Director, President and Chief Executive Officer (Principal Executive Officer)	March 3, 2011
/s/ Richard I. Steinhart **Richard I. Steinhart**	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 3, 2011
/s/ Breaux Castleman **Breaux Castleman**	Chairman of the Board of Directors	March 3, 2011
/s/ Sidney Braginsky **Sidney Braginsky**	Director	March 3, 2011
/s/ George C. Chryssis **George C. Chryssis**	Director	March 3, 2011
/s/ Martin D. Cleary **Martin D. Cleary**	Director	March 3, 2011
/s/ Anne Egger **Anne Egger**	Director	March 3, 2011
/s/ Gerald Wagner, PhD. **Gerald Wagner, PhD.**	Director	March 3, 2011

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. 333-151935, File No. 333-159274 and File No. 333-167113) and on Forms S-8 (File No. 333-136183 and File No. 333-161286) of our reports dated March 2, 2011 with respect to our audits of the balance sheets of MELA Sciences, Inc. as of December 31, 2009 and 2010, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2010, and our audit of the Company's internal control over financial reporting as of December 31, 2010, included in the December 31, 2010 annual report on Form 10-K of MELA Sciences, Inc.

We also consent to the reference to our firm under the heading "Experts" in the Registration Statements on Forms S-3 (File No. 333-139056, File No. 333-145740, File No. 333-151935, File No. 333-159274 and File No. 333-167113).

/s/ EisnerAmper LLP (formerly Eisner LLP)

New York, New York
March 2, 2011

Exhibit 31.1

CERTIFICATION

I, Joseph V. Gulfo, 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/ Joseph V. Gulfo, M.D.

Joseph V. Gulfo, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 3, 2011

Exhibit 31.2

CERTIFICATION

I, Richard I. Steinhart, 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/ Richard I. Steinhart

Richard I. Steinhart
Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Date: March 3, 2011

Exhibit 32.1

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

Each of the undersigned officers of MELA Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's Annual Report on Form 10-K for the period ended December 31, 2010 (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/ Joseph V. Gulfo, M.D.

Joseph V. Gulfo, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

March 3, 2011

/s/ Richard I. Steinhart

Richard I. Steinhart
Vice President & Chief Financial Officer
(Principal Accounting and Financial Officer)

March 3, 2011

* 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.

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Board of Directors

Breaux Castleman
Chairman

Sidney Braginsky

George C. Chryssis

Martin D. Cleary

Anne Egger

Joseph V. Gulfo, MD
President and Chief Executive Officer

Gerald Wagner, PhD

Dan W. Lufkin
Director Emeritus

Executive Officers

Joseph V. Gulfo, MD
President and Chief Executive Officer

Richard I. Steinhart
Vice President, Finance
Chief Financial Officer and Treasurer

Tina Cheng-Avery
Vice President, Commercialization

Nyq Kabelev
Vice President, Research and Development

Investor Information

Shares of MELA Sciences trade on the NASDAQ Capital Market under the ticker symbol MELA.

Transfer Agent

American Stock Transfer & Trust Company
59 Maiden Lane
Plaza Level
New York, NY 10038
Phone: 800-937-5449
Phone: 718-921-8124
http://www.amstock.com

Annual Meeting Date

April 29, 2011

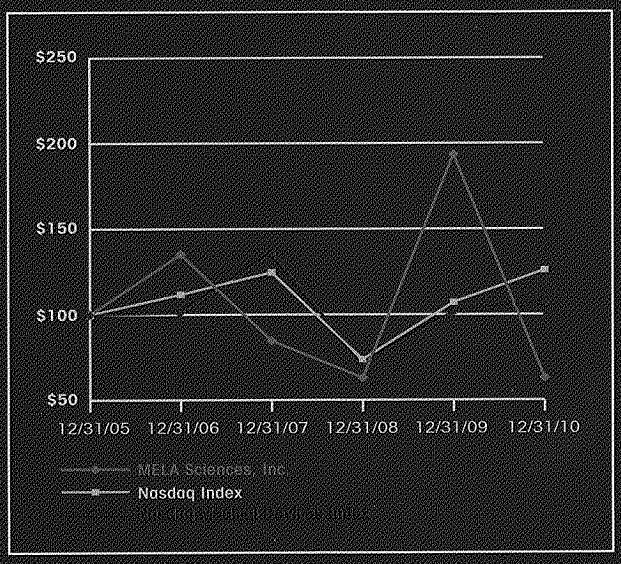
Investor Relations

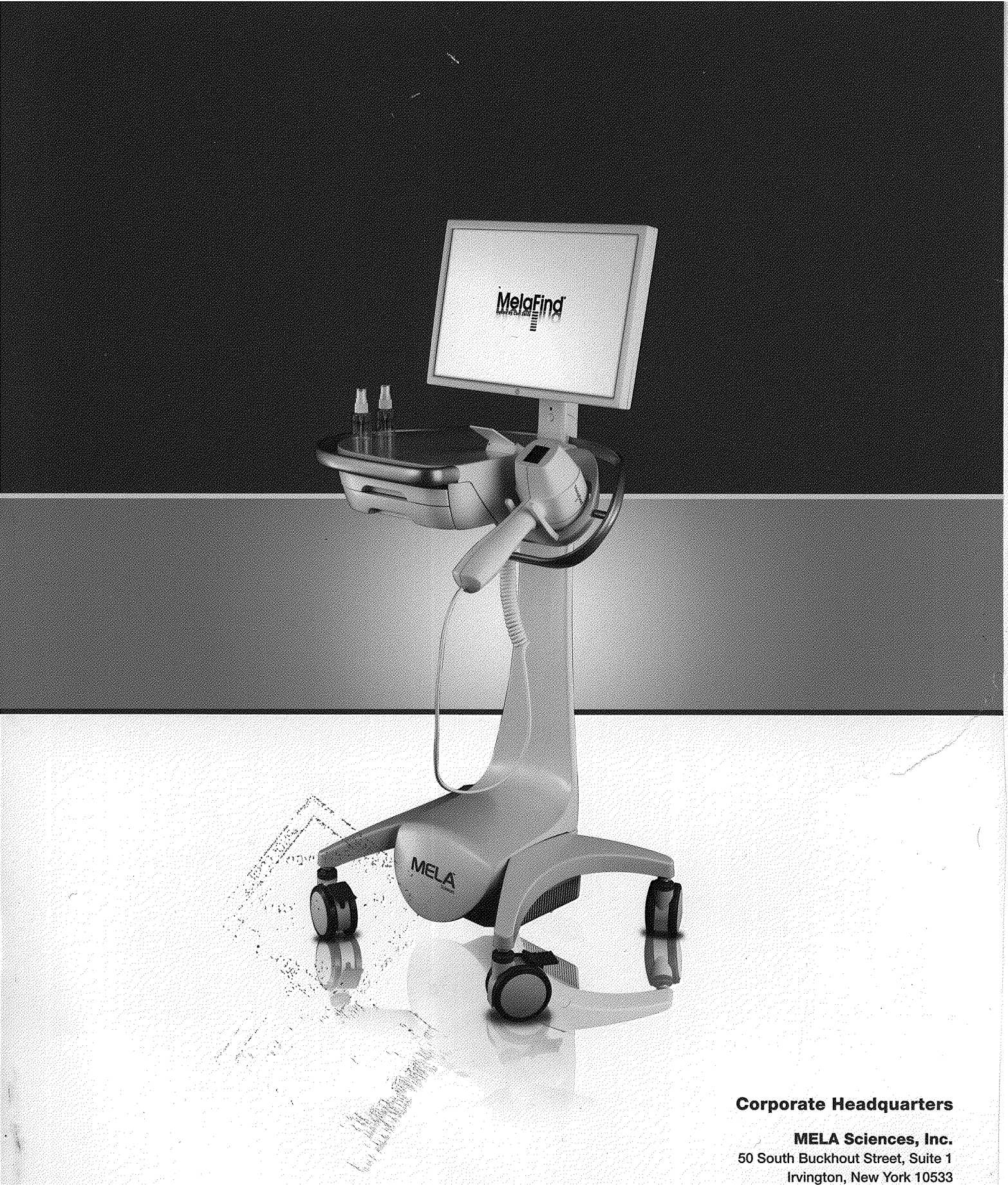
Lazar Partners Ltd.
420 Lexington Avenue, Suite 442
New York, NY 10170
Phone: 646-871-8485
e-mail: dcarey@lazarpartners.com

Independent Auditors

EisnerAmper LLP

Comparison of Cumulative Total Return





Corporate Headquarters

MELA Sciences, Inc.
50 South Buckhout Street, Suite 1
Irvington, New York 10533
United States
Phone: 914-591-3783
e-mail: info@melasciences.com
www.melasciences.com