

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

**FORM S-3
REGISTRATION STATEMENT
UNDER
SECURITIES ACT OF 1933**

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

Delaware
(State or other jurisdiction of
incorporation or organization)

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

**50 South Buckhout Street, Suite 1
Irvington, New York 10533
(914) 591-3783**
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

**Joseph V. Gulfo, M.D.
President and Chief Executive Officer
MELA Sciences, Inc.
50 South Buckhout Street, Suite 1
Irvington, New York 10533
(914) 591-3783**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy To:

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to general Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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 (Do not check if a smaller reporting company) Smaller Reporting Company

CALCULATION OF REGISTRATION FEE

Title of each class of	Amount	Proposed	Amount of
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securities to be registered (1)	to be registered (1)	maximum aggregate offering price per unit (2)	registration fee (3)
Common Stock, par value \$0.001 per share	—	—	—
Warrants	—	—	—
Units	—	—	—
Total	—	\$75,000,000	\$7,515.64

- (1) There are being registered hereunder such indeterminate number of shares of common stock, such indeterminate number of warrants to purchase shares of common stock and such indeterminate number of units as shall have an aggregate initial offering price not to exceed \$75,000,000. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the securities being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.
- (2) The proposed maximum aggregate offering price per class of security will be determined from time to time by the Registrant in connection with the issuance by the Registrant of securities registered hereunder and is not specified as to each class of security pursuant to General II.D. of Form S-3 under the Securities Act.
- (3) Calculated pursuant to Rule 457(o) under the Securities Act. As discussed in the paragraph below, pursuant to Rule 415(a)(6) under the Securities Act of 1933, as amended, this registration statement includes, as of the date of filing of this registration statement, \$19,900,000 of unsold securities that had previously been registered and for which the registration fee had previously been paid. Accordingly, the amount of the registration fee is \$7,515.64 (\$75.0 million – \$19.9 million x \$136.40 per million).

Pursuant to Rule 415(a)(6) of the Securities Act of 1933, as amended, the securities registered pursuant to this registration statement include, as of the date of filing of this registration statement, \$19,900,000 of unsold securities previously registered on the registrant's Registration Statement on Form S-3 (Registration Statement No. 333-167113), which we refer to as the Prior Registration Statement. Pursuant to Rule 415(a)(6), the offering of the unsold securities registered under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of this registration statement. If the registrant sells any of such unsold securities pursuant to the Prior Registration Statement after the date of this filing, and prior to the date of effectiveness, of this registration statement, the Registrant will file a pre-effective amendment to this registration statement which will reduce the number of such unsold securities included on this registration statement and increase the additional securities registered hereon so that the total amount of securities registered hereon will equal \$75,000,000, as reflected in footnote 1 to the table above, and will pay the additional registration fee resulting therefrom.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

[Table of Contents](#)

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 5, 2013

PRELIMINARY PROSPECTUS

\$75,000,000

MELA SCIENCES, INC.

Common Stock, Warrants and Units

We may from time to time sell any combination of securities described in this prospectus, either individually or in units. The aggregate initial offering price of all securities sold by us under this prospectus will not exceed \$75,000,000.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide the specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplement carefully before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

Our common stock is listed on the Nasdaq Capital Market under the symbol "MELA." On June 4, 2013, the last reported sale price of our common stock on the Nasdaq Capital Market was \$1.15 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on the Nasdaq Capital Market or any securities market or other exchange of the securities, if any, covered by the prospectus supplement. If any agents or underwriters are involved in the sale of any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

As of June 5, 2013, the aggregate market value of our outstanding common stock held by non-affiliates was \$49,295,470 based on 43,112,144 shares of outstanding common stock, of which 42,865,626 shares are held by non-affiliates, and a per share price of \$1.15, which was the closing sale price of our common stock as quoted on the Nasdaq Capital Market on June 4, 2013. We have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date hereof.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 2, AS WELL AS THE RISKS DISCUSSED UNDER THE CAPTION "RISK FACTORS" IN DOCUMENTS WE SUBSEQUENTLY FILE WITH THE SECURITIES AND EXCHANGE COMMISSION.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is _____, 2013

TABLE OF CONTENTS

	Page
Business Description	1
Risk Factors	2
Special Note Regarding Forward –Looking Statements	20
Use Proceeds	20
Plan of Distribution	21
Description of Capital Stock	23
Description of Warrants	23
Description of Units	25
Legal Matters	26
Experts	26
Where You Can Find More Information	27
Information Incorporated By Reference	27

ABOUT THIS PROSPECTUS

In this prospectus, unless we indicate otherwise, “we,” “us,” “our,” “the Company” and “MELA” refer to MELA Sciences, Inc.

This prospectus is a part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$75,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading “Where You Can Find More Information.”

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and the accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and the accompanying prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or securities sold on a later date.

This prospectus contains references to our U.S. registered trademarks: MELA®, MELA Sciences®, MelaFind® and MELARecord®. All other trademarks, tradenames and service marks appearing in this prospectus are the property of their respective owners.

BUSINESS DESCRIPTION

We are a medical device company focused on the commercialization of our flagship product, MelaFind[®], and the further design and development of MelaFind[®] and our technology. MelaFind[®] is a non-invasive, point-of-care (in the doctor's office) instrument to aid in the detection of melanoma. MelaFind[®] features a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated classification algorithms, '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.

In November 2011, we received written approval from the U.S. Food and Drug Administration ("FDA") for the MelaFind[®] Pre-Market Approval ("PMA") application and in September 2011 received Conformance Européenne ("CE") Mark approval for MelaFind[®]. On March 7, 2012, we installed the first commercial MelaFind[®] systems, and proceeded with the first phase of the commercial launch of our breakthrough product for melanoma detection.

During the first quarter of 2013, we continued our controlled and deliberate commercial launch of MelaFind[®] by entering into user agreements with dermatologist customers and installing MelaFind[®] systems in the U.S. and Germany, while simultaneously commencing the second phase of the MelaFind[®] commercial launch by focusing on system usage and patient mobilization among our current customers. As of March 31, 2013, user agreements with 138 customers were in place and 126 MelaFind[®] systems were installed, with 12 installations pending scheduling and training of staff. We are currently in discussions with a number of additional dermatologist practices that either have a user agreement currently under evaluation, or have been classified as "highly interested" by the Company. However, just because these potential customers may have expressed interest in obtaining a MelaFind[®] system, there can be no assurance that any of these potential customers will ever sign a user agreement with us. Our rate of placement varies from month to month and may or may not bear any relation to the number of potential customers we may have at any one time. Our placement rate to date has not been at the level initially estimated, due to a number of factors, including the time it takes to properly train doctors and staff for correct usage, our limited marketing to date, and general awareness as to the potential benefits of MelaFind[®]. Our revenues are dependent on the amount of usage generated from our installed systems, which is out of our control as usage (i.e. the number of patients used on and the amount of lesions per patient) ultimately will be determined between the doctor and the individual patients. The financial success of our company will depend on a number of factors, primary among which is our ability to place MelaFind[®] systems, increase the penetration with dermatologists, encourage the usage of these systems, and control our costs. Currently, we cannot determine when we will have sufficient revenues to cover our continuing developmental costs, manufacturing, marketing and other operational expenses.

We were incorporated in the State of New York in 1989 under the name Electro-Optical Sciences, Inc. and subsequently reincorporated under the laws of the State of Delaware in 1997. In April 2010, we changed our name to MELA Sciences, Inc. Our executive offices are located at 50 South Buckhout Street, Suite 1, Irvington, New York 10533. Our telephone number is (914) 591-3783. Our website is www.melasciences.com. The information contained on our website is not a part of this prospectus and should not be relied upon. We have included our website address in this document as an inactive textual reference only.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information contained in this prospectus and in documents that are incorporated by reference into this prospectus. 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 and you might lose all or part of your investment in our securities.

Risks Relating to Our Business

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

Our net loss for the three months ended March 31, 2013 was approximately \$6.5 million, and as of March 31, 2013, we had an accumulated deficit of approximately \$148.7 million. Our research and development expenses may increase in connection with our continued development activities related to MelaFind®. We expect to incur significant sales, marketing, contract-manufacturing and inventory build-up 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 may be unable to continue commercialization and continue development of MelaFind® enhancements or other products without additional funding and we will not be able to achieve significant commercialization without additional funding.

As of March 31, 2013, we had approximately \$21.6 million in cash and cash equivalents. Our operations have consumed substantial amounts of cash over the past several years and we expect that our cash used by operations will increase significantly in each of the next several years. We believe that our available cash and cash equivalents combined with our anticipated revenues will be sufficient to fund our anticipated levels of operations for at least the next twelve months. In the event that the Company is unable to raise additional funds, the Company has the ability and intent to reduce certain discretionary expenditures. However, we will need substantial funds to broaden the commercial expansion of MelaFind®, including further development of a direct sales force and expansion of our contract-manufacturing capacity. We also expect to continue to spend funds on research and development and product enhancements. Our business or operations may change in a manner that would consume available resources more rapidly than we anticipate. The amount of funding we will need will depend on many factors, including:

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

[Table of Contents](#)

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 also may have to reduce marketing, customer support and other resources devoted to our products. 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, or that may require us to grant a security interest in our assets. 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.

We may not be able to make required monthly payments of principal and interest when due under the terms of our loan agreement.

In March 2013, we entered into a Loan and Security Agreement with a venture capital lender in connection with a loan of up to \$10 million. Of the \$10 million loan, \$6 million was funded at closing and we have the option to draw down the remaining \$4 million through March 17, 2014, subject to the satisfaction of meeting certain sales and revenue targets. The loan bears interest at the rate of 10.45% per year and matures on November 1, 2016. During the first 12 months of the loan, only interest will be paid to the lender, and after that, we will be required to make 30 equal payments of principal and interest until maturity. The loan is secured by a general lien against all of our assets, other than our intellectual property assets. If we are unable to make the required principal and interest payments in a timely manner, the lender could declare the loan to be in default and may seize and sell those assets securing the loan, which could have a material adverse effect on our business, financial condition and results of operations.

MelaFind® may not be widely accepted by the dermatological community.

The success of MelaFind® will depend upon the level of acceptance by dermatologists who perform skin examinations and treat 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 a significant number of such recommendations will be obtained. To date, the medical community outside of our customer base has had little exposure to us and MelaFind®. 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 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, dermatologists may remain reluctant to use MelaFind®. Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind® by the dermatological community. Insufficient market acceptance of MelaFind® would have a material adverse effect on our business, financial condition and results of operations.

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

Our future growth and profitability will depend, in large part, on speed and level of market acceptance for the use of MelaFind® among physicians, government and third party payers, and regulators.

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

[Table of Contents](#)

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

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

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

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

As a condition of approval of our PMA, we must conduct a Post-Approval Study evaluating the sensitivity of physicians in diagnosing melanomas and high-grade lesions and the false positive rate after using MelaFind®. Conducting this Post-Approval Study is costly and time consuming.

We are required to submit to the FDA progress reports on this study for every six months during the first two years and annually thereafter. The first progress report was submitted to the FDA in February 2013. If the FDA has questions on the data provided in a progress report, or believes the data are incomplete or insufficient, the agency may request additional information, including through a deficiency letter. The FDA may seek the advice of advisory panels of outside experts when considering the initiation or progress of post-approval studies. If we have not met the study milestones or timeline specified in the study protocol, we must provide a rationale to the FDA in our progress reports. If a change in the study milestones or timeline could significantly affect the outcome of the Post-Approval Study, we will need to submit that revision for the agency's review and approval. We will need to update MelaFind®'s labeling with the results from this study, including any positive or negative results.

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

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

[Table of Contents](#)

The FDA posts information about the status of post-approval studies on its website. These website postings could undermine the credibility of the Company or MelaFind®, or have other collateral effects. For example, the agency will identify the study status as “Progress Inadequate” if the study progress is inconsistent with the protocol, such as if the study is not meeting the enrollment schedule or study timeline, missing timepoint evaluations, if there are poor follow-up rates, or if not all the endpoints are evaluated.

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

The availability of medical insurance coverage and reimbursement for newly approved medical devices is uncertain. In the U.S., physicians and other healthcare providers performing biopsies for clinically atypical skin lesions are generally reimbursed for all or part of the cost of the diagnosis and biopsy by Medicare, Medicaid, or other third party payers. Significant commercial success of MelaFind® in both domestic and international markets may depend on whether third-party coverage and reimbursement are available for services involving MelaFind®.

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

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

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

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

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, according to an industry report, Medicare coverage determinations for medical devices lag 15 months to five years or more behind FDA approval for that device. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and

[Table of Contents](#)

timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state by state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the U.S. Department of Health and Human Services (“HHS”). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations. The length of time it takes for us to obtain a coverage determination may affect the ability of MelaFind® to become commercially viable.

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

We do not know of any product possessing the diagnostic assistance capabilities of MelaFind®. While several companies including Verisante, Scibase and Caliber Imaging and Diagnostic, Inc. (formerly Lucid, Inc.) have technologies that may be used to assist the dermatologist none of these companies' products have undergone the rigors of FDA PMA review and subsequent approval. We believe that other products that enhance the visualization and analysis of potential melanomas have been approved or are under development by: Welch Allyn, Inc.; Heine Optotechnik; 3Gen, LLC; Derma Medical Systems, Inc.; MedX Health; Biomips Engineering, Michelson Diagnostics, Riester, ViseoMed, AG and others. In addition, several companies have developed various dermatological apps for use with an Apple iPhone. The broader market for precision optical imaging devices used for medical diagnosis is intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. We will potentially be subject to competition from major optical imaging companies, such as: Raytheon Corporation, General Electric Co.; Siemens AG; Bayer AG; Olympus Corporation; Carl Zeiss AG Deutschland; and others, each of which manufactures and markets precision optical imaging

[Table of Contents](#)

products for the medical market, and could decide to develop or acquire a product to compete with MelaFind®. These companies enjoy numerous competitive advantages, including:

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

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

If we are unable to establish adequate 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 have a limited sales organization, and have limited experience in the marketing and distribution of MelaFind® or similar devices. To achieve commercial success for MelaFind®, we must develop a full sales and marketing force or enter into arrangements with others to market and sell our products. We have established a small direct sales force to market MelaFind® in the U.S. and Europe (initially in Germany), focused on introducing it at high volume dermatologists' offices and training their staffs in its use. 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 representatives. We can give 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 if we are not able to procure an adequate supply of MelaFind®, our growth could be limited and our business could be harmed.

We have limited experience in manufacturing MelaFind® for commercial distribution. Since we utilize contract manufacturers for our product, we do not have in-house resources and facilities to commercially manufacture MelaFind®. In order to produce MelaFind® in the quantities we anticipate necessary 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.

[Table of Contents](#)

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

The failure by us or our suppliers to produce a sufficient number of MelaFind® devices that can operate according to our specifications could delay the full commercialization of MelaFind®, and would adversely affect both our ability to successfully commercialize MelaFind® and our business, financial condition and results of operations.

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

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

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

- suppliers may make errors in manufacturing components that could negatively impact the effectiveness or safety of our products, or cause delays in shipment of our products;
- we may 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, which would adversely affect both our ability to successfully commercialize MelaFind® and our business, financial condition and results of operations.

[Table of Contents](#)

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

Significant purchases of MelaFind® systems from our contract manufacturers will result in greater amounts of property and equipment on our balance sheet which will lead, to among other things, increased depreciation expenses on our income statement and may affect our return on capital investment.

From time to time we plan to issue significant purchase orders, to be paid and delivered over time, under master production agreements and similar arrangements with our contract manufacturers in order to satisfy the projected placements of MelaFind® systems. Certain purchase orders may be for very substantial amounts, some of which may be in excess of \$1 million, and represent firm commitments to purchase MelaFind® systems (or components thereof). The timing and size of these purchase orders will depend on our market forecasts and our available capital resources. As we purchase larger numbers of MelaFind® systems, the amount of property and equipment on our balance sheet will correspondingly increase. The increased amount of property and equipment on our balance sheet will result in larger amounts of depreciation expense which will impact the amount of net income (loss) reported on our income statement. If we are unable to place purchased MelaFind® systems we may experience expenses for obsolescence. The destruction or loss of any of the placed MelaFind® systems may also result in loss above and beyond the amounts for which they are insured.

Our current business model entails an immediate upfront expense to the Company in connection with the purchase of a MelaFind® system, the cost of which is then offset by an initial installation fee and a future revenue stream to the Company every time the system is used. It may take several years before the anticipated income from a placed MelaFind® system is sufficient to recover the unit's original cost.

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

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

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

Many significant components of the MelaFind® system are manufactured by foreign suppliers and we also market MelaFind® internationally. We may be subject to various import duties applicable to materials manufactured in foreign countries and, in addition, may be affected by various other import and export

[Table of Contents](#)

restrictions, as well as other considerations or developments impacting upon international trade, including economic or political instability, shipping delays and product quotas. These international trade factors may have an adverse impact on the cost of components and the prices we can charge for the MelaFind® system. To the extent that transactions relating to the purchase of components and materials or the sale of products involve currencies other than U.S. dollars, our operating results will be affected by fluctuations in foreign currency exchange rates.

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

Our MelaFind® design incorporates certain unique components, some of which have become obsolete and others of which may, from time-to-time, become obsolete. We will eventually be unable to replace obsolete components and an extensive re-design and re-approval process for MelaFind® will be required in order to utilize substitute components. If we are unable to provide component availability during that re-design and regulatory approval process, or are unable to effectively re-design and complete the re-approval process for MelaFind®, our ability to produce MelaFind® will become impaired, we may incur substantial additional costs and it would have a material adverse effect on our business, financial condition and results of operations. Furthermore, our actions in building inventory of parts that may become obsolete and have to be disposed of at a loss or written-down may add expenses to our operations and reduce our margins.

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

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

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continuous review and periodic inspections by the FDA and other regulatory bodies, including Germany’s Federal Institute for Drugs and Medical Devices. In particular, we and our suppliers are required to comply with the QSR, ISO 13485 and other U.S. and European regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, promotion, distribution, and shipping of MelaFind®. We also will be subject to ongoing U.S. and foreign regulatory requirements, including required submissions of safety and other post-market information and reports and registration and listing requirements. Furthermore, our third-party contract manufacturers will be required to adhere to current cGMP requirements enforced by the FDA as part of QSR, or similar regulations required by regulatory agencies in other countries. The manufacturing facilities of our contract manufacturers must be in full compliance with cGMP requirements 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 (or any applicable foreign rules and regulations), we could be subject to regulatory action of a type described below, which could negatively affect our ability to successfully commercialize MelaFind®. There can be no assurance that the future interpretations of legal

[Table of Contents](#)

requirements made by the FDA or other U.S. or foreign regulatory bodies with possible retroactive effect, or the adoption of new requirements or policies, will not adversely affect us. We may be slow to adapt, or may not be able to adapt, to these changes or new requirements. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other U.S. or foreign regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions:

- warning letters;
- fines and civil penalties;
- unanticipated expenditures;
- withdrawal of approval by the FDA or other regulatory bodies;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer.

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

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

For example, from time to time, legislation is introduced in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

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

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

- billing for services;
- quality of medical equipment and services;

[Table of Contents](#)

- confidentiality, maintenance and security issues associated with medical records and individually identifiable health information;
- false claims; and
- labeling products.

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

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

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act. The legislation imposes significant new excise taxes on medical device transactions. Under the legislation, the total cost to the medical device industry is estimated to be approximately \$20 billion over ten years. In January 2013, a 2.3% excise tax on medical devices went into effect as a component of the Patient Protection and Affordable Care Act. This tax along with the others in the Act will result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our results of operations and our cash flows. Other elements of this legislation such as comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business.

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

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs and; the Civil Monetary Penalties Law, which authorizes HHS to impose civil penalties administratively for fraudulent or abusive acts. Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use of MelaFind® by physicians may dissuade physicians from either purchasing or using MelaFind® and could have a material adverse effect on our ability to successfully commercialize MelaFind®.

The application of the privacy provisions of HIPAA is uncertain.

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

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

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

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

A court could order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing MelaFind®, and/or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

We rely on our patents, patent applications and other intellectual property rights to give us a competitive advantage. Whether a patent is valid, or whether a patent application should be granted, is a complex matter of science and law. Therefore we cannot be certain that, if challenged, our patents, patent applications and/or other intellectual property rights would be upheld. If one or more of those patents, patent applications and other intellectual property rights are invalidated, rejected or found unenforceable, those outcomes could reduce or eliminate any competitive advantage we might otherwise have had.

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

Our long-term success is dependent, in large part, on the successful commercialization of MelaFind® and the further design and development of MelaFind® and our technology. The product development process is time-consuming, unpredictable and costly. There can be no assurance that we will be able to develop or acquire new products, successfully complete any related clinical trials, obtain the necessary

[Table of Contents](#)

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

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

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

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

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

We may be adversely affected by a data center failure.

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

We may 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

[Table of Contents](#)

transmission of confidential information, security breaches could damage our reputation and expose us to a risk of loss, or to litigation and possible liability. Our business may be materially adversely affected if our security measures do not prevent security breaches. In addition, such information may be subject to HIPAA privacy and security regulations, the potential violation of which may trigger concerns by healthcare providers, which may adversely impact our business, financial condition and results of operations.

We are dependent upon telecommunications and the internet.

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

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

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

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

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

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

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

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

We expect to expand our operations and grow our research and development, product development, administrative and marketing 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.

[Table of Contents](#)

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 commercialize MelaFind® in the U.S. marketplace.

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

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

Risks Relating to our Common Stock

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

The Sarbanes-Oxley Act of 2002 (“SOX”), as well as rules implemented by the SEC, the Public Company Accounting Oversight Board and the NASDAQ Stock Market, have required changes in the corporate governance practices of public companies. Monitoring compliance with the existing rules and implementing changes required by these rules may increase our legal and financial compliance costs, divert management attention from operations and strategic opportunities, and make legal, accounting and administrative activities more time-consuming and costly. Since 2008, we have retained a consultant experienced in SOX that assists us in the process of 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, 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 which could have an adverse effect on our stockholders ability to sell their stock.

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

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

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

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

- failure of any of our products to achieve commercial success;
- the timing of regulatory approval for our future products;
- results of our research and development efforts and our clinical trials;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the U.S. and foreign countries;
- our ability to manufacture our products to commercial standards;
- developments concerning our clinical collaborators, suppliers or marketing partners;
- changes in financial estimates or recommendations by securities analysts;
- public concern over our products;
- developments or disputes concerning patents or other intellectual property rights;
- product liability claims and litigation against us or our competitors;
- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of third-party reimbursement in the U.S. and other countries;
- changes in accounting principles or practices;
- general economic, industry and market conditions; and
- future sales of our common stock.

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained or incorporated by reference in this prospectus that are not historical facts are forward-looking. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements include, without limitation, our expectations regarding sales, earnings or other future financial performance and liquidity, conduct and completion of clinical trials, product introductions, entry into new geographic regions, and general optimism about future operations or operating results. Some of these statements can be identified by the use of forward-looking terminology such as “prospects,” “outlook,” “believes,” “estimates,” “intends,” “may,” “will,” “should,” “anticipates,” “expects” or “plans,” or the negative or other variation of these or similar words, or by discussion of trends and conditions, strategy or risks and uncertainties.

These forward-looking expectations are based on current assumptions within the bounds of management’s knowledge of our business and operations and which management believes are reasonable. These assumptions are subject to risks and uncertainties, and actual results could differ materially from expectations because of issues and uncertainties such as those listed under the caption “Risk Factors” and elsewhere in this prospectus and in documents incorporated into this prospectus which, among others, should be considered in evaluating our future financial performance. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements in this prospectus. Readers are advised to consult any further disclosures we may make on related subjects in subsequent reports filed with the SEC.

Additional information on factors that may affect our business and financial results can be found in our filings with the SEC. All forward-looking statements should be considered in light of these risks and uncertainties. We assume no responsibility to update forward-looking statements made in this prospectus.

USE OF PROCEEDS

Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities under this prospectus for general corporate purposes, which may include, among other things, working capital, acquisition or investments in our business, research and development and capital expenditures. Pending the application of the net proceeds, we intend to invest the net proceeds in short-term, investment grade, interest-bearing securities.

PLAN OF DISTRIBUTION

Unless otherwise set forth in a prospectus supplement accompanying this prospectus, we may sell the offered securities in any one or more of the following ways from time to time:

- through agents;
- to or through underwriters;
- through dealers;
- directly to purchasers; or
- through remarketing firms.

The prospectus supplement with respect to the offered securities will set forth the terms of the offering of the offered securities, including:

- the name or names of any underwriters, dealers or agents;
- the purchase price of the offered securities and the proceeds to us from such sale;
- any underwriting discounts and commissions or agency fees and other items constituting underwriters' or agents' compensation;
- any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange on which such offered securities may be listed.

Any initial public offering price, discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

The distribution of the offered securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices.

Offers to purchase the offered securities may be solicited by agents designated by us from time to time. Any agent involved in the offer or sale of the offered securities will be named, and any commissions payable by us to such agent will be set forth, in the applicable prospectus supplement. Unless otherwise indicated in the prospectus supplement, the agent will be acting on a reasonable best efforts basis for the period of its appointment.

If underwriters are used in the sale of the offered securities, the offered securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at fixed public offering prices or at varying prices determined by the underwriters at the time of sale. The offered securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters. Unless otherwise indicated in the applicable prospectus supplement, the underwriters are subject to certain conditions precedent and will be obligated to purchase all the offered securities of a series if they purchase any of the offered securities.

If a dealer is used in the sale of the offered securities, we will sell the offered securities to the dealer as principal. The dealer may then resell the offered securities to the public at varying prices to be determined by the dealer at the time of resale. The name of the dealer and the terms of the transaction will be set forth in the applicable prospectus supplement.

Offers to purchase the offered securities may be solicited directly by us and the sale thereof may be made by us directly to institutional investors or others. The terms of any such sales will be described in the applicable prospectus supplement.

[Table of Contents](#)

The offered securities may also be offered and sold by a remarketing firm in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as agents for us. These remarketing firms will offer or sell the offered securities pursuant to the terms of the offered securities. Any remarketing firm will be identified and the terms of its agreements, if any, with us and its compensation will be described in the applicable prospectus supplement.

We may authorize underwriters, dealers and agents to solicit from third parties offers to purchase the offered securities under contracts providing for payment and delivery on future dates. The applicable prospectus supplement will describe the material terms of these contracts, including any conditions to the purchasers' obligations, and will include any required information about commissions we may pay for soliciting these contracts.

In connection with the sale of the offered securities, agents, underwriters, dealers or remarketing firms may receive compensation from us or from purchasers of the offered securities for whom they act as agents in the form of discounts, concessions or commissions. Underwriters may sell the offered securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Agents, underwriters, dealers and remarketing firms that participate in the distribution of the offered securities, and any institutional investors or others that purchase offered securities directly and then resell the securities, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the securities by them may be deemed to be underwriting discounts and commissions under the Securities Act.

The maximum commission or discount to be received by any member of the Financial Industry Regulatory Authority ("FINRA") or independent broker-dealer will not be greater than 8% of the initial gross proceeds received by us for the sale of any securities being registered pursuant to SEC Rule 415.

Agents, underwriters, dealers and remarketing firms may be entitled under relevant agreements entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act or to contribution with respect to payments which the agents, underwriters or dealers may be required to make.

Each series of the offered securities will be a new issue and, other than the shares of common stock which are listed on the Nasdaq Capital Market, will have no established trading market. Any underwriters to whom we sell the offered securities for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We may elect to list any series of offered securities on an exchange, and in the case of common stock, on any additional exchange, but, unless otherwise specified in the applicable prospectus supplement, we will not be obligated to do so. We cannot predict the liquidity of the trading market for any of the offered securities.

In connection with an offering, the underwriters may purchase and sell the offered securities in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of offered securities than they are required to purchase in an offering. Stabilizing transactions consist of certain bids or purchases made for the purpose of preventing or retarding a decline in the market price of the offered securities while an offering is in progress.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the underwriters have repurchased offered securities sold by or for the account of that underwriter in stabilizing or short-covering transactions.

[Table of Contents](#)

These activities by the underwriters may stabilize, maintain or otherwise affect the market price of the offered securities. As a result, the price of the offered securities may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time. These transactions may be effected on an exchange or automated quotation system, if the offered securities are listed on that exchange or admitted for trading on that automated quotation system, or in the over-the-counter market or otherwise.

Underwriters, dealers, agents and remarketing firms, or their affiliates, may be customers of, engage in transactions with, or perform services for, us and our subsidiaries in the ordinary course of business.

DESCRIPTION OF CAPITAL STOCK

The following information describes our common stock and provisions of our Fifth Amended and Restated Certificate of Incorporation, as amended, and our Third Amended and Restated By-laws as in effect as of the date of this prospectus. This description is only a summary.

Common Stock

We are authorized to issue up to 95,000,000 shares of common stock, \$0.001 par value per share. As of April 30, 2013, there were 43,037,144 shares of our common stock issued and outstanding.

Holders of our common stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Holders of common stock are entitled to receive dividends, if declared by our Board of Directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of common stock are entitled to share ratably in our assets once our debts are paid. All shares of common stock that are outstanding as of the date of this prospectus are fully-paid and non-assessable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, 59 Maiden Lane, New York, New York 10038.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

[Table of Contents](#)

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of warrant that describes the terms of the series of warrants we are offering before the issuance of the related series of warrants. The following summaries of material terms and provisions of the warrants are subject to, and qualified in their entirety by reference to, all the provisions of the warrant. We urge you to read the applicable prospectus supplements related to the particular series of warrants that we sell under this prospectus, as well as the complete warrant.

General

The warrants may be issued under a warrant agreement independently or together with any other securities offered by any prospectus supplement and may be attached to or separate from such other offered securities. If warrants are offered, the applicable prospectus supplement will describe the designation and terms of the warrants, including:

- the offering price, if any;
- the designation and terms of the common stock purchasable upon exercise of the warrants;
- if applicable, the date on and after which the warrants and the related offered securities will be separately transferable;
- the number of shares of common stock purchasable upon exercise of one warrant and the initial price at which the shares may be purchased upon exercise;
- the date on which the right to exercise the warrants will commence and expire;
- a discussion of certain United States Federal income tax considerations;
- the call provisions, if any;
- the currency, currencies or currency units in which the offering price, if any, and exercise price are payable;
- any antidilution provisions of the warrants; and
- any other terms of the warrants.

The shares of common stock issuable upon exercise of the warrants will, when issued in accordance with the warrant agreement, be fully paid and nonassessable.

Exercise of Stock Warrants

Warrants may be exercised by surrendering the warrant to the warrant agent, which may be the Company, with the form of election to purchase properly completed and signed and by payment in full of the exercise price, as set forth in the applicable prospectus supplement. Upon receipt of the exercise paperwork, the warrant agent will requisition from the transfer agent for the common stock for issuance and delivery to or upon the written order of the exercising warrant holder, a certificate representing the number of shares of common stock purchased. If less than all of the warrants evidenced by any warrant are exercised, the warrant agent will deliver to the exercising warrant holder a new warrant representing the unexercised warrants.

[Table of Contents](#)

No Rights as Stockholders

Holders of warrants will not be entitled, by virtue of being such holders, to vote, to consent, to receive dividends, to receive notice as stockholders with respect to any meeting of stockholders for the election of our directors or any other matter, or to exercise any rights whatsoever as our stockholders.

Outstanding Warrants

In connection with our May 2009 financing with Kingsbridge Capital Limited, we issued a 5 year warrant to Kingsbridge to purchase up to 200,000 shares of our common stock at an exercise price of \$11.35 per share. These warrants are currently outstanding.

In connection with our March 2013 \$10 million loan with Hercules Technology Growth Capital, Inc., we issued a 5 year warrant to Hercules to purchase up to 693,202 shares of our common stock at an exercise price of \$1.118 per share. These warrants were issued on April 26, 2013 and are currently outstanding.

DESCRIPTION OF UNITS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we sell under this prospectus, as well as the complete unit agreement and any supplemental agreements that contain the terms of the units.

General

We may issue units comprised of common stock and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

[Table of Contents](#)

We will describe in the applicable prospectus supplement the terms of the series of units, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under “Description of Capital Stock” and “Description of Warrants” will apply to each unit and to any common stock or warrant included in each unit, respectively.

Issuance in Series

We may issue units in such amounts and in numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

LEGAL MATTERS

For the purposes of this offering, is passing upon the validity of the securities offered by this prospectus.

EXPERTS

The financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K, for the year ended December 31, 2012 have been audited by EisnerAmper LLP, an independent registered public accounting firm as stated in their report incorporated herein by reference, which report has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Federal securities laws require us to file information with the SEC concerning our business and operations. Accordingly, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's public reference rooms, including those located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on public reference rooms. Our SEC filings are also available to the public from the SEC's web site at <http://www.sec.gov>.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities being offering under this prospectus. This prospectus, which is a part of that registration statement, does not include all the information contained in the registration statement and its exhibits. For further information with respect to our company and the securities, you should consult the registration statement and its exhibits. Statements contained in this prospectus concerning the provisions of any documents are summaries of those documents, and we refer you to the document filed with the SEC for more information. The registration statement and any of its amendments, including exhibits filed as a part of the registration statement or an amendment to the registration statement, are available for inspection and copying as described above.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" certain information we file with them in this prospectus. This means that we can disclose important information to you by referring you to the other information we have filed with the SEC. The information that we incorporate by reference is considered to be part of this prospectus. Information that we file later with the SEC will automatically update and supersede this information. Further, all filings we make under the Exchange Act prior to the termination of the offering shall be deemed to be incorporated by reference into this prospectus. The following documents filed by us with the SEC and any future filings under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (File No. 000-51481) made prior to the termination of this offering are incorporated by reference:

- our Annual Report on Form 10-K for the year ended December 31, 2012 (including information specifically incorporated by reference into our Form 10-K from our Proxy Statement for our 2013 Annual Meeting of Stockholders);
- our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013;
- our Current Reports on Forms 8-K filed on January 17, 2013, February 12, 2013, March 5, 2013, March 18, 2013, March 20, 2013, April 29, 2013 and April 30, 2013; and
- the description of our common stock contained in our registration statement on Form 8-A and any amendments or reports filed for the purpose of updating such description.

This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. Reports we file with the SEC after the date of this prospectus may also contain information that updates, modifies or is contrary to information in this prospectus or in documents incorporated by reference in this prospectus. Investors should review these reports as they may disclose a change in our business, prospectus, financial condition or other affairs after the date of this prospectus.

[Table of Contents](#)

We will also provide paper copies of our filings free of charge upon written or oral request. You can request a free copy of the above filings or any filings subsequently incorporated by reference into this prospectus by writing or calling us at:

MELA Sciences, Inc.
50 South Buckhout Street, Suite 1
Irvington, New York 10533
Attention: Richard I. Steinhart
(914) 591-3783

WE HAVE NOT AUTHORIZED ANY DEALER, SALES PERSON OR OTHER PERSON TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS. THIS PROSPECTUS IS NOT AN OFFER OF THESE SECURITIES IN ANY STATE WHERE AN OFFER IS NOT PERMITTED. THE INFORMATION IN THIS PROSPECTUS IS CURRENT AS OF THE DATE OF THIS PROSPECTUS AND YOU SHOULD NOT ASSUME THAT THIS PROSPECTUS IS ACCURATE AS OF ANY OTHER DATE.

MELA SCIENCES, INC.

\$75,000,000

Common Stock
Warrants
Units

PROSPECTUS

_____, 2013

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses Of Issuance And Distribution

The following table sets forth the costs and expenses, other than placement agent commissions, if any, which will be paid by us, in connection with the registration of the securities being registered. All amounts are estimated, except the SEC registration fee:

SEC registration fee	\$ 7,515.64
Accounting fees and expenses	\$10,000.00
Legal fees and expenses	\$20,000.00
Printing and miscellaneous expenses	\$ 5,000.36
Total	\$42,516.00

Item 15. Indemnification Of Directors And Officers

Our amended and restated certificate of incorporation includes provisions that eliminate, to the fullest extent permitted by the Delaware General Corporation Law (the “DGCL”), the personal liability of our directors to us or our stockholders for monetary damages for breach of fiduciary duty as a director. Our amended and restated bylaws require us to indemnify our directors and officers to the fullest extent permitted by the DGCL. Pursuant to these provisions, we have entered into indemnity agreements with certain of our directors.

Pursuant to Section 145 of the DGCL, a corporation generally has the power to indemnify its present and former directors, officers, employees and agents against expenses incurred by them in connection with any suit to which they are, or are threatened to be made, a party by reason of their serving in such positions so long as they acted in good faith and in a manner that they reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action, had no reasonable cause to believe their conduct was unlawful.

These provisions do not eliminate the duty of care, and in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, may remain available under Delaware law. Each director will continue to be subject to liability for breach of the director’s duty of loyalty to us or our stockholders, for acts or omissions not in good faith or involving intentional misconduct or knowing violations of law, for unlawful payments of dividends or unlawful stock repurchases or redemptions under Section 174 of the DGCL or for any transaction from which the director derived an improper personal benefit. These provisions also generally do not affect a director’s responsibilities under any other laws, such as the federal securities laws.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the “Securities Act”) may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Table of Contents

Item 16. Exhibits

No.	Description
1.1	Form of Underwriting Agreement ¹
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company ²
3.2	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation of the Company*
3.3	Third Amended and Restated By-laws of Company ³
4.1	Specimen Common Stock Certificate ³
4.2	Form of Common Stock Warrant Agreement and Warrant Certificate ¹
4.3	Form of Unit Agreement ¹
5.1	Opinion of Goodwin Procter LLP*
23.1	Consent of Goodwin Procter LLP (included in Exhibit 5.1)*
23.2	Consent of EisnerAmper LLP*
24.1	Power of Attorney (included as part of the signature page of this Registration Statement)

* Filed herewith.

¹ To be filed, if necessary, subsequent to the effectiveness of this registration statement by an amendment to this registration statement or incorporated by reference pursuant to a Current Report on Form 8-K in connection with the offering of securities.

² Incorporated by reference to our Registration Statement on Form S-3 (File No. 333-167113), as filed on May 26, 2010.

³ Incorporated by reference to our Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on August 8, 2005.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933.

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or

[Table of Contents](#)

high and of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Table of Contents

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act will be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Irvington, New York, on this 5th day of June, 2013.

MELA SCIENCES, INC.

By: /s/ JOSEPH V. GULFO, M.D.
Joseph V. Gulfo, M.D.
Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Joseph V. Gulfo and Richard I. Steinhart and each of them, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including, without limitation, post-effective amendments) to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as each of them might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the date indicated.

<u>Name and Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JOSEPH V. GULFO, M.D.</u> Joseph V. Gulfo, M.D.	President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	June 5, 2013
<u>/s/ RICHARD I. STEINHART</u> Richard I. Steinhart	Sr. VP, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	June 5, 2013
<u>/s/ ROBERT CORADINI</u> Robert Coradini	Director	June 5, 2013
<u>/s/ ANNE EGGER</u> Anne Egger	Director	June 5, 2013
<u>/s/ MARK FABIANI</u> Mark Fabiani	Director	June 5, 2013
<u>/s/ MINDY MEADS</u> Mindy Meads	Director	June 5, 2013
<u>/s/ DAVID K. STONE</u> David K. Stone	Director	June 5, 2013

[Table of Contents](#)

<u>/s/ KATHRYN SWINTEK</u> Kathryn Swintek	Director	June 5, 2013
<u>/s/ LUANN VIA</u> LuAnn Via	Director	June 5, 2013

Exhibit Index

No.	Description
1.1	Form of Underwriting Agreement ¹
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company ²
3.2	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation of the Company*
3.3	Third Amended and Restated By-laws of Company ³
4.1	Specimen Common Stock Certificate ³
4.2	Form of Common Stock Warrant Agreement and Warrant Certificate ¹
4.3	Form of Unit Agreement ¹
5.1	Opinion of Goodwin Procter LLP*
23.1	Consent of Goodwin Procter LLP (included in Exhibit 5.1)*
23.2	Consent of EisnerAmper LLP*
24.1	Power of Attorney (included as part of the signature page of this Registration Statement)

* Filed herewith.

¹ To be filed, if necessary, subsequent to the effectiveness of this registration statement by an amendment to this registration statement or incorporated by reference pursuant to a Current Report on Form 8-K in connection with the offering of securities.

² Incorporated by reference to our Registration Statement on Form S-3 (File No. 333-167113), as filed on May 26, 2010.

³ Incorporated by reference to our Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on August 8, 2005.

**CERTIFICATE OF AMENDMENT OF CERTIFICATE OF INCORPORATION
OF
MELA SCIENCES, INC.**

It is hereby certified that:

1. The name of the corporation (hereinafter called the "corporation") is MELA Sciences, Inc.

2. The Certificate of Incorporation of the corporation is hereby amended by striking out the first paragraph of Article III thereof and by substituting in lieu thereof the following new first paragraph of Article III:

"The total number of shares of stock that the Corporation shall have authority to issue is 105,000,000 consisting of 95,000,000 shares of Common Stock, \$0.001 par value per share, and 10,000,000 shares of Preferred Stock, \$0.10 par value per share."

3. The amendment of the Certificate of Incorporation herein certified has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

4. This amendment of the Certificate of Incorporation shall be effective on April 25, 2013.

Signed on: April 25, 2013

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

Name: Joseph V. Gulfo, M.D.

Title: President and Chief Executive Officer

June 5, 2013

Mela Sciences, Inc.
50 South Buckhout Street, Suite 1
Irvington, New York 10533

Re: Securities Being Registered under Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to you in connection with your filing on the date hereof of a Registration Statement on Form S-3 (as amended or supplemented, the "Registration Statement") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of up to \$75,000,000 of any combination of (i) common stock, par value \$0.01 per share (the "Common Stock"), of Mela Sciences, Inc., a Delaware corporation (the "Company"), (ii) warrants to purchase Common Stock ("Warrants"), and (iii) units comprised of Common Stock and Warrants ("Units"). The Common Stock, Warrants and Units are sometimes referred to collectively herein as the "Securities." The Registration Statement provides that the Securities may be offered separately or together, in separate series, in amounts, at prices and on terms to be set forth in one or more prospectus supplements (each a "Prospectus Supplement") to the prospectus contained in the Registration Statement.

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers and other inquiries of the Company.

The opinions set forth below are limited to the Delaware General Corporation Law (which includes reported judicial decisions interpreting the Delaware General Corporation Law), the law of New York, and the federal law of the United States. Without limiting the generality of the foregoing, we express no opinion with respect to (i) state securities or "blue sky" laws, or (ii) state or federal antitrust laws.

For purposes of the opinions set forth below, without limiting any other exceptions or qualifications set forth herein, we have assumed that after the issuance of any Securities offered pursuant to the Registration Statement, the total number of issued shares of Common Stock, together with the total number of shares of such stock issuable upon the exercise, exchange, conversion or settlement, as the case may be, of any exercisable, exchangeable or convertible security (including without limitation any Unit), as the case may be, then outstanding, will not exceed the total number of authorized shares of Common Stock under the Company's certificate of incorporation as then in effect (the "Charter").

For purposes of the opinions set forth below, we refer to the following as the “Future Authorization and Issuance” of Securities:

- with respect to any of the Securities, (a) the authorization by the Company of the amount, terms and issuance of such Securities (the “Authorization”) and (b) the issuance of such Securities in accordance with the Authorization therefor upon the receipt by the Company of the consideration (which, in the case of shares of Common Stock, is not less than the par value of such shares) to be paid therefor in accordance with the Authorization;
- with respect to Warrants or Units, (a) the authorization, execution and delivery by the Company and the other parties thereto of any agreement under which such Securities are to be issued and (b) the establishment of the terms of such Securities, and the execution and delivery of such Securities, in conformity with any applicable agreement under which such Securities are to be issued and applicable law.

Based upon the foregoing, and subject to the additional qualifications set forth below, we are of the opinion that:

1. Upon the Future Authorization and Issuance of shares of Common Stock, such shares of Common Stock will be validly issued, fully paid and nonassessable.
2. Upon the Future Authorization and Issuance of Warrants, such Warrants will be valid and binding obligations of the Company.
3. Upon the Future Authorization and Issuance of Units, such Units will be valid and binding obligations of the Company.

The opinions expressed above are subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors and to general principles of equity.

This opinion letter and the opinions it contains shall be interpreted in accordance with the Legal Opinion Principles issued by the Committee on Legal Opinions of the American Bar Association’s Business Law Section as published in 53 Business Lawyer 831 (May 1998).

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption “Legal Matters” in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Goodwin Procter LLP

GOODWIN PROCTER LLP

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement of MELA Sciences, Inc. on Form S-3, to be filed on or about June 5, 2013 of our report dated March 4, 2013, on our audits of the financial statements as of December 31, 2011 and 2012 and for each of the years in the three-year period ended December 31, 2012, and the effectiveness of MELA Sciences, Inc.'s internal control over financial reporting as of December 31, 2012, which reports were included in the Annual Report on Form 10-K filed March 4, 2013. We also consent to the reference to our firm under the caption "Experts" in the Registration Statement on Form S-3.

/s/ EisnerAmper LLP

EisnerAmper LLP
New York, New York
June 5, 2013