

PROSPECTUS SUPPLEMENT
(To Prospectus Dated June 1, 2010)

6,100,000 Shares



Common Stock

We are offering 6,100,000 shares of our common stock pursuant to this prospectus supplement and accompanying prospectus.

Our common stock is quoted on the Nasdaq Capital Market under the symbol "MELA." On February 11, 2013, the last reported sale price of our common stock was \$1.69 per share.

Investing in our common stock involves a high degree of risk. Please read the information contained in and incorporated by reference under the heading "[Risk Factors](#)" beginning on page S-3 of this prospectus supplement, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement.

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 supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ 1.30	\$7,930,000
Underwriting discount and commissions	\$ 0.078	\$ 475,800
Proceeds, before expenses, to us	\$ 1.222	\$7,454,200

The underwriter expects to deliver the shares against payment on February 15, 2013.

Cowen and Company

February 12, 2013

TABLE OF CONTENTS

Prospectus Supplement

	<u>Page</u>
ABOUT THIS PROSPECTUS SUPPLEMENT	S-i
PROSPECTUS SUPPLEMENT SUMMARY	S-1
THE OFFERING	S-2
RISK FACTORS	S-3
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	S-4
USE OF PROCEEDS	S-4
DETERMINATION OF OFFERING PRICE	S-4
DESCRIPTION OF COMMON STOCK	S-5
DILUTION	S-5
UNDERWRITING	S-6
LEGAL MATTERS	S-9
EXPERTS	S-9
WHERE YOU CAN FIND MORE INFORMATION	S-9
INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE	S-10

Prospectus

BUSINESS DESCRIPTION	1
RISK FACTORS	2
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	25
USE OF PROCEEDS	25
PLAN OF DISTRIBUTION	27
DESCRIPTION OF CAPITAL STOCK	29
DESCRIPTION OF WARRANTS	29
DESCRIPTION OF UNITS	31
LEGAL MATTERS	32
EXPERTS	32
WHERE YOU CAN FIND MORE INFORMATION	33
INFORMATION INCORPORATED BY REFERENCE	33

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is the prospectus supplement, which describes the specific terms of the securities we are offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. This prospectus supplement and the accompanying prospectus and the documents incorporated by reference herein and therein include important information about us, our securities being offered and other information you should know before investing. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus and any related free writing prospectus that we authorized to be delivered to you, as well as the additional information described under the captions “Where You Can Find More Information” on page S-9 and “Incorporation of Documents by Reference” on page S-10 of this prospectus supplement before investing in our securities.

To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission (“SEC”) before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in this prospectus supplement or the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus, any related free writing prospectus that we authorized to be distributed to you and the documents incorporated by reference herein and therein. We have not, and underwriter has not, authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus supplement, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus and any related free writing prospectus that we have authorized to be delivered to you is accurate only as of their respective dates, regardless of the time of delivery of such documents or of any sale of securities. Our business, financial condition, results of operations and prospects may have changed since those dates. You should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus outside the United States. Furthermore, you should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

Unless the context requires otherwise, in this prospectus supplement and the accompanying prospectus the terms “MELA,” “the Company,” “we,” “us,” “our” and similar names refer to MELA Sciences, Inc.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus supplement and in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all the information that may be important to you in deciding whether to invest in our common stock. After you read this summary, you should read and consider carefully the more detailed information and financial statements and related notes that we include in and/or incorporate by reference into this prospectus supplement and the accompanying prospectus, especially the sections entitled “Risk Factors” before making an investment decision. If you invest in our securities, you are assuming a high degree of risk.

Our Company

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 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.

We received the U.S. Food and Drug Administration’s approval of the Pre-Market Approval application for MelaFind[®] in November 2011, and in September 2011, we received Conformite Europeenne (“CE”) Mark approval for MelaFind[®]. We initiated a controlled launch of MelaFind[®] in selected U.S. and German markets in March 2012. In March 2012, we began generating revenues from MelaFind[®]. We have continued our controlled launch of MelaFind[®] with additional installations of MelaFind[®] systems in both the U.S. and Germany. In the U.S., MelaFind[®] systems were placed principally in the Northeast with additional installations in certain Southern, Mid-Western and Western states.

In June 2012, we entered into a sales agreement with Cowen and Company, LLC, the book-running managing underwriter in this offering, to sell shares of our common stock through an “at-the-market” equity offering program (the “ATM Program”). As of February 11, 2013, we have sold approximately 6.6 million shares of our common stock through the ATM Program for gross proceeds of approximately \$14.4 million. In conjunction with this offering, we have terminated the ATM Program.

In February 2013, we signed a non-binding term sheet with a venture capital lender for a loan of up to \$10 million. Of the \$10 million, it is anticipated that \$6 million will be funded in March 2013 and we will 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. It is anticipated that the loan will mature 42 months from the initial closing and bear interest at the rate of 10.45% per year. The term sheet contemplates that during the first 12 months of the loan, only interest will be paid to the lender and after that we will make 30 equal payments of principal and interest until maturity. The loan would be secured by a general lien against all of our assets, other than our intellectual property assets. In addition, the lender will have a security interest in the proceeds of the sale of any of our intellectual property assets. In connection with the loan, the lender will receive a warrant to purchase that number of shares of our common stock equal to 775,000 divided by the to-be-determined exercise price of the warrant. The loan is subject to satisfactory completion of the lender’s due diligence and the execution of definitive loan documents and is conditioned upon the Company having raised \$12.5 million in equity proceeds since January 1, 2013. There can be no assurance that the loan will be consummated or that the material terms of the loan will be as described.

Corporate Information

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 supplement and should not be relied upon. We have included our website address in this document as an inactive textual reference only.

THE OFFERING

Common stock offered by us in this prospectus supplement	6,100,000 shares
Common stock to be outstanding immediately after this offering assuming the sale of all shares in this offering	43,037,144 shares
Price per share	\$1.30
Use of proceeds	We intend to use the net proceeds from this offering to continue the commercial launch of MelaFind® in the U.S. and the European Union, for continued research & development activities and for general corporate purposes, including working capital.
Risk Factors	Before buying any shares you should read the discussion of risks related to an investment in our common stock, see “Risk Factors” beginning on page S-3 of this prospectus supplement and page 2 of the accompany prospectus, as well as the risks discussed under the caption “RISK FACTORS” in our Annual Report on Form 10-K for the year ended December 31, 2011, as revised or supplemented by our quarterly reports on Form 10-Q, as subsequently filed with the SEC, each of which is incorporated by reference in this prospectus supplement.
Nasdaq Capital Market symbol	“MELA”

The number of shares of our common stock to be outstanding immediately after this offering as shown above is based on 36,937,144 shares of common stock outstanding as of February 11, 2013. This number of shares does not include the following:

- up to 2,412,877 shares of common stock that may be issued upon the exercise of outstanding options as of February 11, 2013 pursuant to our stock option plans at a weighted-average exercise price of \$4.02 per share;
- up to 200,000 shares of common stock issuable upon the exercise of outstanding warrants as of February 11, 2013 at an exercise price of \$11.35 per share; and
- 75,000 shares of common stock issuable under our stock option plan pursuant to the terms of a consulting agreement.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully consider the risk factors below and beginning on page 2 of the accompanying prospectus, as well as the risks discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2011, as revised or supplemented by our quarterly reports on Form 10-Q, as subsequently filed with the SEC, each of which is incorporated by reference into this prospectus supplement. Such risks and uncertainties are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of these 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 common stock.

Risks Related to this Offering

Management will have broad discretion as to the use of the proceeds from this offering.

Our management will have broad discretion as to the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds.

Investors in this offering will pay a much higher price than the book value of our common stock.

You will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering because the price per share of our common stock being offered hereby is substantially higher than the book value per share of our common stock. Assuming all shares in the offering are sold at \$1.30 per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$0.64 per share in the net tangible book value of the common stock. See “Dilution” on page S-5 of this prospectus supplement for a more detailed discussion of the dilution you will incur in this offering.

A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. Immediately following this offering, we will have outstanding an aggregate of 43,037,144 shares of common stock. A substantial majority of the outstanding shares of our common stock are, and all of the shares sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act of 1933.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained or incorporated by reference in this prospectus supplement and the accompanying prospectus and the documents incorporated by reference herein and therein 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, market acceptance of MelaFind®, entry into new geographic regions, conduct and completion of clinical trials 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. Investors should not place undue reliance on forward-looking statements.

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 the issues and uncertainties specifically discussed in the “Risk Factors” sections of this prospectus supplement, the accompanying prospectus and periodic reports incorporated herein and elsewhere in this prospectus supplement, the accompanying prospectus and documents incorporated into this prospectus supplement and the accompanying prospectus which, among others, should be considered in evaluating our future financial performance. Factors that might cause such a difference include whether Melafind® achieves market acceptance or becomes commercially viable. 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 supplement. 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 supplement.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of our common stock in this offering will be approximately \$7.3 million, after deducting the underwriting discount and commissions and all estimated offering expenses that are payable by us. We intend to use the net proceeds from this offering to continue the commercial launch of MelaFind® in the U.S. and the European Union, for continued research & development activities and for general corporate purposes, including working capital.

Pending the application of the net proceeds, we intend to invest the net proceeds in short-term, investment grade, interest-bearing securities.

DETERMINATION OF OFFERING PRICE

We determined the offering price of the common stock being offered by this prospectus supplement principally by negotiations between us and the underwriter and our consideration of the closing prices (including high, low and average prices) and trading volumes of our common stock on the Nasdaq Capital Market preceding the date we determined the offering price. No independent appraisal or valuation was obtained to determine the offering price.

DESCRIPTION OF COMMON STOCK

A description of the material terms and provisions of our common stock is set forth under the heading “Description of Capital Stock” starting on page 29 of the accompanying prospectus.

DILUTION

Our net tangible book value as of September 30, 2012, was approximately \$17.5 million, or \$0.56 per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. Assuming the sale by us of 6,100,000 shares at the public offering price of \$1.30 per share, and after deducting estimated commissions and estimated offering expenses, our net tangible book value as of September 30, 2012, would have been approximately \$24.7 million, or \$0.66 per share of common stock. This represents an immediate increase in net tangible book value of \$0.10 per share to our existing stockholders and an immediate dilution in net tangible book value of \$0.64 per share to purchasers of our common stock in this offering, as illustrated by the following table:

Assumed public offering price per share		\$1.30
Net tangible book value per share as of September 30, 2012	\$0.56	
Increase per share attributable to new investors after giving effect to this offering	<u>\$0.10</u>	
Pro forma net tangible book value per share after this offering		<u>\$0.66</u>
Pro forma dilution in net tangible book value per share to new investors		<u>\$0.64</u>

The number of shares of common stock outstanding used for existing stockholders in both the table and calculations above is based on 31,323,910 shares of common stock outstanding as of September 30, 2012. This number of shares does not include the following:

- up to 2,259,506 shares of common stock that may be issued upon the exercise of outstanding options as of September 30, 2012 pursuant to our stock option plans at a weighted-average exercise price of \$4.16 per share; and
- up to 200,000 shares of common stock issuable upon the exercise of outstanding warrants as of September 30, 2012 at an exercise price of \$11.35 per share.

UNDERWRITING

We and the underwriter for the offering named below have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase from us the number of shares of our common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
Cowen and Company, LLC	6,100,000

The underwriting agreement provides that the obligations of the underwriter are subject to certain conditions precedent and that the underwriter has agreed to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased.

We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments the underwriter may be required to make in respect thereof.

The underwriter is offering the shares, subject to prior sale, when, as and if issued to and accepted by it, subject to approval of legal matters by its counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts. The following table shows the public offering price, underwriting discount and proceeds, before expenses to us.

The expenses of the offering, not including the underwriting discounts and commissions, payable by us are estimated to be \$175,000, which includes approximately \$50,000 that we have agreed to reimburse the underwriter for legal fees and other expenses incurred in connection with this offering.

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ 1.30	\$7,930,000
Underwriting discount	\$ 0.078	\$ 475,800
Proceeds, before expenses, to us	\$ 1.222	\$7,454,200

The underwriter proposes to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus supplement. If all of the shares are not sold at the public offering price, the underwriter may change the offering price and other selling terms.

Discretionary Accounts. The underwriter does not intend to confirm sales of the shares to any accounts over which it has discretionary authority.

Stabilization. In connection with this offering, the underwriter may engage in stabilizing transactions, syndicate covering transactions, and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. If the underwriter has a naked short position, the position would be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Table of Contents

These stabilizing transactions and syndicate covering transactions may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making. In connection with this offering, the underwriter may engage in passive market making transactions in our common stock on the Nasdaq Capital Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Lock-up Agreements. Pursuant to certain "lock-up" agreements, we and our executive officers and directors have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act of 1933 relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC, for a period of 90 days after the date of the pricing of the offering. The 90-day restricted period will be automatically extended if (i) during the last 17 days of the 90-day restricted period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the 90-day restricted period, we announce that we will release earnings results or become aware that material news or a material event will occur during the 16-day period beginning on the last day of the 90-day restricted period, in either of which case the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit us, among other things and subject to restrictions, to: (a) issue common stock or options pursuant to employee benefit plans, (b) issue common stock upon exercise of outstanding options or warrants (c) issue securities in connection with acquisitions or similar transactions, or (d) file registration statements on Form S-8. The exceptions permit parties to the "lock-up" agreements, among other things and subject to restrictions, to: (a) make certain gifts, (b) if the party is a corporation, partnership, limited liability company or other business entity, make transfers to any shareholders, partners, members of, or owners of similar equity interests in, the party, or to an affiliate of the party, if such transfer is not for value, and (c) if the party is a corporation, partnership, limited liability company or other business entity, make transfers in connection with the sale or transfer of all of the party's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the party's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by the "lock-up" agreement. In addition, the lock-up provision will not restrict broker-dealers from engaging in market making and similar activities conducted in the ordinary course of their business.

Cowen and Company, LLC, in its sole discretion, may release our common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our common stock and other securities from lock-up agreements, Cowen and Company, LLC will consider, among other factors, the holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time of the request.

United Kingdom. The underwriter has represented and agreed that:

Table of Contents

- it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of section 102B of the Financial Services and Markets Act 2000 (as amended) (FSMA) except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority (FSA);
- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to us; and
- it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

Switzerland. The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

European Economic Area. In relation to each Member State of the European Economic Area (Iceland, Norway and Lichtenstein in addition to the member states of the European Union) that has implemented the Prospectus Directive (each, a Relevant Member State), the underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of the securities to the public in that Relevant Member State prior to the publication of a prospectus in relation to the securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of the securities to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts; or
- in any other circumstances which do not require the publication by the issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any securities under, the offer contemplated in this prospectus will be deemed to have represented, warranted and agreed to and with us and each underwriter that:

- it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive; and
- in the case of any securities acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (1) the securities acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the underwriter has been given to the offer or resale; or (2) where securities have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the

[Table of Contents](#)

offer of those securities to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of the provisions in the two immediately preceding paragraphs, the expression an “offer of the securities to the public” in relation to the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Electronic Offer, Sale and Distribution of Shares. A prospectus in electronic format may be made available on the websites maintained by the underwriter and the underwriter may distribute prospectuses electronically. Internet distributions will be allocated by the underwriter. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus supplement, the accompanying prospectus or the registration statement of which the accompanying prospectus forms a part, has not been approved or endorsed by us or the underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other Relationships. The underwriter and its affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

LEGAL MATTERS

For the purposes of this offering, Golenbock Eiseman Assor Bell & Peskoe LLP, New York, New York is passing upon the validity of the common stock being offered hereby. LeClairRyan, A Professional Corporation, New York, New York is acting as counsel for the underwriter in connection with this offering.

EXPERTS

The financial statements of MELA Sciences, Inc. as of December 31, 2011 and 2010, and for each of the years in the three-year period ended December 31, 2011, and management’s assessment of the effectiveness of internal control over financial reporting as of December 31, 2011 have been incorporated by reference herein and in the registration statement in reliance upon the report of EisnerAmper LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934. 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. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. 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 website at <http://www.sec.gov>.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” certain information we file with them in this prospectus supplement. 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 supplement. Information that we file later with the SEC will automatically update and supersede this information. Further, all filings we make under the Securities Exchange Act of 1934, prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus supplement. 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 Securities Exchange Act of 1934 (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, 2011 (including information specifically incorporated by reference into our Form 10-K from our Proxy Statement for our 2012 Annual Meeting of Stockholders);
- our Quarterly Report on Form 10-Q for the quarters ended March 31, 2012, June 30, 2012 and September 30, 2012;
- our Current Reports on Form 8-K filed on January 11, 2012, March 7, 2012, March 22, 2012, April 27, 2012, June 15, 2012, October 15, 2012, November 7, 2012, January 17, 2013 and February 12, 2013;
- our Proxy Statement for our 2012 Annual Meeting of Stockholders; 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 supplement may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus supplement. Reports we file with the SEC after the date of this prospectus supplement may also contain information that updates, modifies or is contrary to information in this prospectus supplement or in documents incorporated by reference in this prospectus supplement. 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 supplement.

Our website is www.melasciences.com. Our website contains copies of our filings with the SEC. We will also provide electronic or paper copies of our filings free of charge upon written or oral request. Information contained on our website or any other website is not incorporated into this prospectus supplement and does not constitute a part of this prospectus supplement. You can request a free copy of the above filings or any filings subsequently incorporated by reference into this prospectus supplement by writing or calling us at:

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

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 May 24, 2010, the last reported sale price of our common stock on the Nasdaq Capital Market was \$6.11 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.

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 June 1, 2010

TABLE OF CONTENTS

	Page
Business Description	1
Risk Factors	2
Special Note Regarding Forward —Looking Statements	25
Use Proceeds	25
Plan of Distribution	27
Description of Capital Stock	29
Description of Warrants	29
Description of Units	31
Legal Matters	32
Experts	32
Where You Can Find More Information	33
Information Incorporated By Reference	33

ABOUT THIS PROSPECTUS

In this prospectus, unless we indicate otherwise, “we,” “us,” “our,” “the Company” and “MELA” refer to MELA Sciences, Inc. MELA Sciences, Inc. was formerly known as Electro-Optical 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.

[Table of Contents](#)

This prospectus contains references to our U.S. registered trademark: MelaFind®. 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 design, development and commercialization of a non-invasive, point-of-care instrument to assist in the early diagnosis of melanoma. Our flagship product, MelaFind®, features a hand-held imaging device that emits light of multiple wavelengths to capture images of suspicious pigmented skin lesions and extract data. The data are then analyzed utilizing image processing classification algorithms, ‘trained’ on our proprietary database of melanomas and benign lesions, to provide information to assist in the management of the patient, including information useful in the decision of whether to biopsy the lesion. We currently do not have any commercialized products or any significant source of revenue.

The MelaFind® pre-market approval (“PMA”) application was filed in June 2009 and is under review at the U.S. Food and Drug Administration (“FDA”). The pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a Protocol Agreement. In addition, the MelaFind® PMA has been granted Expedited Review by the FDA. The Company is actively working with the FDA during the review process. On March 19, 2010 the Company received a series of questions from the FDA and was notified that the MelaFind® PMA was not approvable at that time. In addition, the Company was advised that the review process had been extended by a period of up to 180 days following the submission of our response to the FDA action letter. Since receiving the questions from the FDA on March 19, the Company has had a series of interactions with the FDA. A draft response was submitted to the FDA in mid-April. The Company also had an in-person meeting with the FDA to review its draft response and to clarify several questions. The final formal response to all questions provided by the FDA was submitted to the FDA on May 7, 2010 and the Company was subsequently informed by the FDA that the MelaFind® PMA would be reviewed by the General and Plastic Surgery Devices Panel appointed by the FDA on August 26, 2010.

Upon obtaining approval from the FDA, we plan to launch MelaFind® commercially in the United States. We are also concurrently using our efforts to obtain a CE Mark that will facilitate commercialization in Europe and other countries.

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

We currently do not have any commercialized products or any significant source of revenue. We have invested substantially all of our time and resources over the last eight years in developing MelaFind®. MelaFind® may require additional development and clinical evaluation and it will require regulatory approval, significant marketing efforts and substantial additional investment before it can provide us with any revenue. On June 9, 2009 the MelaFind® PMA was filed to the FDA. Our efforts may not lead to commercially successful products for a number of reasons, including:

- we may not be able to obtain regulatory approvals for MelaFind®, or the approved indication may be narrower than we seek;
- MelaFind® may not prove to be safe and effective in clinical trials to the FDA's satisfaction;
- physicians may not receive any reimbursement from third-party payers, or the level of reimbursement may be insufficient to support widespread adoption of MelaFind®;
- we may experience delays in our continuing development program;
- any products that are approved may not be accepted in the marketplace by physicians or patients;
- we may not have adequate financial or other resources to complete the continued development or to commence the commercialization of MelaFind® and we will not have adequate financial or other resources to achieve significant commercialization of MelaFind®;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost; and
- rapid technological change may make our technology and products obsolete.

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

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

We do not have the necessary regulatory approvals to market MelaFind® in the U.S. or in any foreign market. We plan initially to launch MelaFind®, once approved, in the U.S. The regulatory approval process for MelaFind® in the U.S. involves, among other things, successfully completing clinical trials and obtaining PMA approval from the FDA. The PMA process requires us to prove the safety and effectiveness of MelaFind® to the FDA's satisfaction. This process is expensive and uncertain, and requires detailed and comprehensive scientific and human clinical data. FDA review may take years after a PMA application is filed. The FDA may never grant approval. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

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

No precedent has been established for FDA approval of a device such as MelaFind® to assist in determining the appropriateness of biopsies of suspicious pigmented skin lesions. While the Company believes that results from the MelaFind® pivotal trial support a favorable PMA review, the FDA may not consider the data gathered in the trial sufficient to support approval of a PMA. On March 19, 2010 the Company received a series of questions from the FDA and was notified that the MelaFind® PMA was not approvable at that time. In addition, the Company was advised that the review process had been extended by a period of up to 180 days following the submission of our response to the FDA action letter. While the Company had a series of interactions with the FDA in mid-April and submitted a formal response to all questions provided by the FDA, there is no assurance that the FDA will consider the Company's response sufficient to support approval of the PMA. The FDA may determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or even years while the trials are conducted and the data acquired are submitted in an amendment to the PMA. The occurrence of unexpected findings in connection with any subsequent clinical trial that may be required by the FDA may prevent or delay obtaining PMA approval, and may adversely affect coverage or reimbursement determinations. If we are unable to complete subsequent clinical trials necessary to successfully support the MelaFind® PMA application, our ability to commercialize MelaFind®, and our business, financial condition, and results of operations would be materially adversely affected, thereby threatening our ability to continue operations.

If MelaFind® is approved by the FDA, it may be approved only for narrow indications.

Even if approved, MelaFind® may not be approved for the indications that are necessary or desirable for successful commercialization. Our preference is to obtain a broad indication for use in assisting in the evaluation of almost all pigmented melanomas (other than those on palms, soles of the feet, in or near the eye, and inaccessible areas such as the edge of the nose). The final MelaFind® lesion classifier may not be able to identify the maximum number of types of melanoma possible. The indications for use must specify those lesion types for which the classifier has not been trained. Approximately five percent of melanoma lesions may be

[Table of Contents](#)

amelanotic, meaning they are not pigmented. These lesions cannot be differentiated by MelaFind[®], which will be restricted to pigmented lesions. Approximately ten percent of pigmented melanoma lesions are nodular, a type of melanoma that is often missed by dermatologists in early stages. If nodular melanoma lesions are not sufficiently well-represented in the MelaFind[®] training database, the classifier may not differentiate nodular melanomas from non-melanomas with sufficient sensitivity and specificity. If we restrict the indications for use of MelaFind[®] to exclude certain melanoma lesion types, in addition to the other restrictions, then the size of the market for MelaFind[®] and the rate of acceptance of MelaFind[®] by physicians may be adversely affected.

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

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

The availability of medical insurance coverage and reimbursement for newly approved medical devices is uncertain. In the U.S., physicians and other healthcare providers performing biopsies for suspicious skin lesions are generally reimbursed for all or part of the cost of the diagnosis and biopsy by Medicare, Medicaid, or other third-party payers.

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

Medicare reimburses for medical devices in a variety of ways, depending on where and how the device is used. However, Medicare only provides reimbursement if the Centers for Medicare and Medicaid Services (“CMS”) determines that the device should be covered and that the use of the device is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor (formerly called carriers and fiscal intermediaries), a private contractor that processes and pays claims on behalf of CMS for the

[Table of Contents](#)

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, but it is unclear how these new provisions will be implemented. Coverage presupposes that the device has been cleared or approved by the FDA and further, that the coverage will be no broader than the approved intended uses of the device as approved or cleared by the FDA, but coverage can be narrower. A coverage determination may be so limited that relatively few patients will qualify for a covered use of the device. Should a very narrow coverage determination be made for MelaFind®, it may undermine the commercial viability of MelaFind®.

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, according to an industry report, Medicare coverage determinations for medical devices lag 15 months to five years or more behind FDA approval for that device. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state by state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the U.S. Department of Health and Human Services (“HHS”). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations.

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

We began operations in December 1989. At that time we provided research services, mostly to U.S. government agencies, on classified projects. We have financed our operations primarily through the sale of our equity securities and have devoted substantially all of our resources to research and development relating to MelaFind®. Our net loss for the year ended December 31, 2009 was approximately \$18.5 million and our net loss for the three months ended March 31, 2010 was approximately \$5.1 million. As of March 31, 2010, we had an accumulated deficit of approximately \$84.3 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind®. If we receive PMA approval for MelaFind® from the FDA, we expect to incur significant sales, marketing expenses and manufacturing expenses which will require additional funding. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders’ equity.

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

We do not know of any product possessing the diagnostic assistance capabilities of MelaFind®. We believe that other products that enhance the visualization and analysis of potential melanomas have been approved or are under development by: Welch Allyn, Inc.; Heine Optotechnik; 3Gen, LLC; Derma Medical Systems, Inc.; Medical High Technologies S.P.A.; ZN Vision Technologies AG; Polartechnics, Ltd.; Astron Clinica (now owned by Biocompatibles International), Ltd.; Biomips Engineering, SciBase AB, Balter Medical, Michelson Diagnostics and others. The broader market for precision optical imaging devices used for medical diagnosis is intensely competitive, subject to rapid change, and significantly affected by new product

[Table of Contents](#)

introductions and other market activities of industry participants. If our products are approved for marketing, we will potentially be subject to competition from major optical imaging companies, such as: Raytheon Corporation, General Electric Co.; Siemens AG; Bayer AG; Eastman Kodak Company; Welch Allyn, Inc.; Olympus Corporation; Carl Zeiss AG Deutschland; and others, each of which manufactures and markets precision optical imaging products for the medical market, and could decide to develop or acquire a product to compete with MelaFind®. These companies enjoy numerous competitive advantages, including:

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

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

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

The precision optical imaging field is subject to rapid technological change and product innovation. MelaFind® is based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies. Companies in the medical device industry with significantly greater financial, technical, research, marketing, sales and distribution and other resources have expertise and interest in the exploitation of computer-aided diagnosis, medical imaging, and other technologies MelaFind® utilizes.

Some of these companies are working on potentially competing products or therapies, including confocal microscopy (a type of scanning microscopy for 3-dimensional specimens, which produces blur-free images at various depths), various forms of spectroscopy (a study of the way molecules absorb and emit light), other imaging modalities, including molecular imaging in which tagged antibodies search for cancer cell antigens, and molecular and genetic screening tests. Molecular-based approaches are being investigated; Dermtech is exploring Messenger RNA analysis of surface cells, for example. Several additional approaches to detecting Melanoma have been identified. Balter Medical (Norway) uses 'Optical Transfer Diagnosis' to identify Melanomas. The technology measures how much light is absorbed in healthy versus diseased tissue to determine whether cancer is present. Raytheon Corporation, partnered with Arizona Cancer Center, utilizes satellite-based remote imaging technology in detecting skin changes that could indicate the presence of cancer. Vanderbilt University has introduced technology called 'Confocal Raman Micro-Spectroscopy'. The technology uses a reflective laser to produce a molecular fingerprint of the underlying tissue to indicate the presence or absence of disease. In addition, the National Institutes of Health and other supporters of cancer research are presumptively seeking ways to improve the diagnosis or treatment of melanoma by sponsoring

[Table of Contents](#)

corporate and academic research. Researchers at Ben Gurion University in Israel announced a new device that detects cancerous skin tumors not visible to the naked eye. The Optical Spectro-Polarimetric Imaging (OSPI) instrument reportedly diagnosed 73 types of lesions, some of them cancerous, in initial testing. Michelson Diagnostics Ltd, a UK based developer and manufacturer, announced that the FDA has awarded it 510(k) clearance for its VivoSight™ OCT scanning product. VivoSight™ is a Multi-Beam OCT system indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body. There can be no assurance that one or more of these companies will not succeed in developing or marketing technologies and products or services that demonstrate better safety or effectiveness, superior clinical results, greater ease of use or lower cost than MelaFind®, or that such competitors will not succeed in obtaining regulatory approval for introducing or commercializing any such products or services prior to us. FDA approval of a commercially viable alternative to MelaFind® produced by a competitor could significantly reduce market acceptance of MelaFind®. Any of the above competitive developments could have a material adverse effect on our business, financial condition, and results of operations. There is no assurance that products, services, or technologies introduced prior to or subsequent to the commercialization of MelaFind® will not render MelaFind® less marketable or obsolete.

For any additional clinical trials required for MelaFind® by the FDA or with respect to clinical trials relating to the development of our core technology for other applications, we depend on clinical investigators and clinical sites and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

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

In addition to the foregoing, any additional clinical studies for MelaFind® which are required by the FDA and any clinical trials relating to the development of the Company's core technology for other applications may be delayed or halted, or be inadequate to support PMA approval, for numerous other reasons, including, but not limited to, the following:

[Table of Contents](#)

- the FDA, an Institutional Review Board (“IRB”) or other regulatory authorities place our clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patient follow-up is not at the rate we expect;
- IRBs and third-party clinical investigators delay or reject our trial protocol;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical trials or manufacturing facilities, among other things, require us to undertake corrective action or suspend or terminate our clinical trials, or invalidate our clinical trials;
- changes in governmental regulations or administrative actions; and
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness.

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

Even if Medicare covers a device for certain uses, that does not mean that the level of reimbursement will be sufficient for commercial success. We expect to experience pricing pressures in connection with the commercialization of MelaFind® and our future products due to efforts by private and government-funded payers to reduce or limit the growth of healthcare costs, the increasing influence of health maintenance organizations, and additional legislative proposals to reduce or limit increases in public funding for healthcare services. Private payers, including managed care payers, increasingly are demanding discounted fee structures and the assumption by healthcare providers of all or a portion of the financial risk. Efforts to impose greater discounts and more stringent cost controls upon healthcare providers by private and public payers are expected to continue. Payers frequently review their coverage policies for existing and new diagnostic tools and can, sometimes without advance notice, deny or change their coverage policies. Significant limits on the scope of services covered or on reimbursement rates and fees on those services that are covered could have a material adverse effect on our ability to commercialize MelaFind® and therefore, on our liquidity and our business, financial condition, and results of operations.

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

[Table of Contents](#)

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

To date, only those patients who were treated by physicians involved in our clinical trials have been evaluated using MelaFind® and even if we obtain regulatory approval, patients with suspicious lesions and physicians evaluating suspicious lesions may not endorse MelaFind®. Physicians tend to be slow to change their diagnostic and medical treatment practices because of perceived liability risks arising from the use of new products. Physicians may not utilize MelaFind® until there is long-term clinical evidence to convince them to alter their existing methods of diagnosing or evaluating suspicious lesions and there are recommendations from prominent physicians that MelaFind® is effective. We cannot predict the speed at which physicians may adopt the use of MelaFind®. By limiting the capital cost of MelaFind® to the physician, we believe we will accelerate its adoption and usage. However, by charging on a per patient basis we will increase the initial capital burden on the Company. If MelaFind® receives the appropriate regulatory approvals but does not achieve an adequate level of acceptance by patients, physicians and healthcare payers, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of MelaFind® will depend on a number of factors, including:

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

The success of MelaFind® will depend upon the acceptance by dermatologists and other physicians who perform skin examinations and treat skin disorders, including industry opinion leaders, that the evaluation information provided by MelaFind® is medically useful and reliable. We will be subject to intense scrutiny before physicians will be comfortable incorporating MelaFind® in their diagnostic approaches. We believe that recommendations by respected physicians will be essential for the development and successful marketing of MelaFind®; however, there can be no assurance that any such recommendations will be obtained. To date, the medical community outside the limited circle of certain dermatologists specializing in melanoma has had little exposure to us and MelaFind®. Because the medical community is often skeptical of new companies and new technologies, we may be unable to gain access to potential customers in order to demonstrate the operation and effectiveness of MelaFind®. Even if we gain access to potential customers, no assurance can be given that members of the dermatological, or later the general practice, medical community will perceive a need for or accept MelaFind®. In particular, given the potentially fatal consequences of failing to detect melanoma at the early, curable stages,

[Table of Contents](#)

practitioners may remain reluctant to rely upon MelaFind® even after we receive approval from the FDA for marketing the product. Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind®. Insufficient market acceptance of MelaFind® would have a material adverse effect on our business, financial condition and results of operations.

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

As of March 31, 2010, we had \$30 million in cash and cash equivalents. Our operations have consumed substantial amounts of cash for each of the last eight years. The Company will require additional funds to pursue regulatory approvals and to achieve significant commercialization of MelaFind®. However, there can be no assurances that the Company will be able to raise additional capital in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term.

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

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

If we are unable to obtain adequate financing on a timely basis, we may be required to significantly curtail or cease one or more of our development and marketing programs. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise pursue on our own. We also may have to reduce marketing, customer support and other

[Table of Contents](#)

resources devoted to our products. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience ownership dilution, could experience declines in our share price and the terms of any new equity securities may have preferences over our common stock.

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

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

We will need to contract with third parties in order to sell and install our products in larger markets, including non-specialist dermatologists and primary care physicians. To the extent that we enter into arrangements with third parties to perform marketing and distribution services domestically or internationally, 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.

Our business model may not generate sufficient revenues in order to create a sustainable business.

Under our current business model, we plan to place MelaFind® systems in physician's offices for a modest placement fee. We will then sell an electronic patient card to physicians designed for a single use patient exam. There can give no assurance that our business model will be successful and that physicians or patients will buy these cards in sufficient quantities to create a sustainable business.

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

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

We currently outsource production to contract manufacturers. Any difficulties in the ability of third-party manufacturers to supply devices of the quality, at the times, and in the quantities we need, could have a material adverse effect on our business, financial condition, and results of operations. Similarly, when we enter into contracts for the third-party manufacture of our devices, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Manufacturers often encounter difficulties in scaling up production of new products, including problems involving product yields, controlling and anticipating product costs, quality control and assurance, component supply, and shortages of qualified personnel. We cannot assure you that the third-party contract manufacturers with whom we have developed or are developing relationships will have or sustain the ability to produce the quantities of MelaFind® needed for development or commercial sales, or will be willing to do so at prices that allow MelaFind® to compete successfully in the market.

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

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

[Table of Contents](#)

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

Our manufacturing efforts currently rely on several vendors for critical materials: FillFactory, a subsidiary of Cypress Semiconductor Corp., to manufacture and supply the complementary metal oxide semiconductor sensor in MelaFind[®], on Carl Zeiss Jena GmbH (“Zeiss”) for lens and lens objective assemblies, A/B Electronics, AAEON, AmeriCad, Applied Image, EpiGap, Lamothermic Precision, Canvys Electronics, Sandisk, SL Power Electronics and others to provide services or components of our devices. We are working with ASKION in Germany, which specializes in precision optics for the provision of the hand-held imaging devices. In addition, we are utilizing Nexcore Technology Inc., an FDA good manufacturing practices (“GMP”) compliant and certified ISO13485 and ISO9001 original equipment manufacturer of medical devices in New Jersey, to provide the assembled MelaFind[®] carts and tested MelaFind[®] systems.

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

- suppliers may make errors in manufacturing components that could negatively impact the effectiveness or safety of our products, or cause delays in shipment of our products;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- we may have difficulty locating and qualifying alternative suppliers for our sole-source suppliers;
- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

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

[Table of Contents](#)

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

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

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

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continuous review and periodic inspections by the FDA and other regulatory bodies. In particular, we and our suppliers are required to comply with the QSR and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, promotion, distribution, and shipping of MelaFind®, and with record keeping practices. We also will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports and registration and listing requirements. To the extent that we contract with third parties to manufacture some of our products, our manufacturers will be required to adhere to current cGMP requirements enforced by the FDA as part of QSR, or similar regulations required by regulatory agencies in other countries. The manufacturing facilities of our contract manufacturers must be in full compliance with cGMP requirements before approval for marketing. The FDA enforces the QSR and other regulatory requirements through unannounced inspections.

[Table of Contents](#)

If we are found to be deficient in cGMP or QSR, we could be subject to FDA action of a type described below, which could negatively affect our ability to commercialize MelaFind®. There can be no assurance that the future interpretations of legal requirements made by the FDA or other regulatory bodies with possible retroactive effect, or the adoption of new requirements or policies, will not adversely affect us. We may be slow to adapt, or may not be able to adapt, to these changes or new requirements. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions:

- warning letters;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve MelaFind®;
- withdrawal of approval by the FDA or other regulatory bodies;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

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

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

From time to time, legislation is introduced in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacture and marketing of a medical device. Additionally, healthcare is heavily regulated by the federal government, and by state and local governments. The federal laws and regulations affecting healthcare change constantly, thereby increasing the uncertainty and risk associated with any healthcare related venture, including our business and MelaFind®. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

The federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the 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

[Table of Contents](#)

fraudulent or abusive practices, including by way of example, the Anti-Kickback Law, the Anti-Physician Referral Law, commonly referred to as Stark, the Anti-Inducement Law, the Civil Money Penalty Law, and the laws that authorize the OIG to exclude healthcare providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights, which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). All of the aforementioned are agencies within HHS. Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Public Health Service within HHS under the Public Health Service Act, the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under Medicaid and other state sponsored or funded programs and their internal laws regulating all healthcare activities.

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

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

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

Healthcare policy changes, including legislation recently enacted by the U.S. Congress to reform the U.S. healthcare system, may have a material adverse effect on us.

Recently, new legislation was adopted to implement significant reforms to the healthcare system in the United States. This legislation imposes an excise tax on medical device makers. This tax could result in a significant increase in our tax burden, which could have a material, negative impact on our Company. Various healthcare reform proposals have also emerged at the state level. We cannot predict how healthcare reform initiatives and subsequent regulations, if any, will be implemented at the U.S. federal or state level, or the effect any new legislation or regulation will have on us. Significant changes to the healthcare system in the United States may increase operational and other costs, and could materially adversely affect our business and results of operations.

[Table of Contents](#)

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

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

The application of the privacy provisions of HIPAA is uncertain.

HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates “covered entities” (insurers, 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 will likely be contractually required to physically safeguard the integrity and security of the patient information that we or our physician customers receive, store, create or transmit. If we fail to adhere to our contractual commitments, then our physician customers may be subject to civil monetary penalties, and this could adversely affect our ability to market MelaFind®. We also may be liable under state laws governing the privacy of health information.

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

[Table of Contents](#)

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

Any infringement or misappropriation claim could cause us to incur significant costs, could place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign MelaFind® to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing MelaFind®, and/or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

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

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

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

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

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if MelaFind® causes, or merely appears to have caused, an injury or if a patient alleges that MelaFind® failed to provide appropriate evaluation information on a lesion where melanoma was subsequently found to be present. Claims may be made by patients, healthcare providers or others involved with MelaFind®. MelaFind® will require PMA approval prior to commercialization in the U.S. The clinical studies of MelaFind® are considered by the FDA as “Non-Significant Risk”. Consequently, the trials are conducted under the auspices of an abbreviated Investigational Device Exemption. We therefore only maintain limited domestic clinical trial liability insurance, as required by certain clinical sites. We have obtained clinical trial liability insurance in certain European countries where required by statute or clinical site policy. Although we have general liability insurance that we believe is appropriate, and anticipate obtaining adequate product liability insurance before commercialization of MelaFind®, this insurance is and will be subject to deductibles and coverage limitations. Our anticipated product liability insurance may not be available to us in amounts and on acceptable terms, if at all, and if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage, or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

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

Insurance and surety companies have reassessed many aspects of their business and, as a result, may take actions that could negatively affect our business. These actions could include increasing insurance premiums, requiring higher self-insured retentions and deductibles, reducing limits, restricting coverages, 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

[Table of Contents](#)

a single facility. Our prospective failure to maintain off-site copies of information contained in our MelaFind® database, or our inability to use alternative sites in the event we experience a natural disaster, hardware or software malfunction or other interruption of our data center could adversely impact our business, financial condition and results of operations. While the Company does provide off-site back-up for its critical data which we believe to be sufficient to meet our needs, there can be no assurance that our current plan can anticipate every possible eventuality.

We may be adversely affected by breaches of online security.

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

We are dependent upon telecommunications and the internet.

Presently, there is no connection between the MelaFind® hand-held imaging device and the central server in our offices. However, if in the future a connection between the MelaFind® hand-held imaging device and the central server in our offices is established, it will be dependent on the internet. We may use the internet as a medium to provide quality control calibration services to physicians. We also plan to use the internet to inform the public about the availability of our products and to market to and communicate with physicians who are potential or actual customers. Our success will therefore depend in part on the continued growth and use of the internet. If our ability to use the internet fails, it may materially adversely affect our business.

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

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

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

All of our operations are conducted at a single building in Irvington, New York. We take precautions to safeguard our facility, including insurance, health and safety protocols, contracted off-site engineering services, and storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage 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.

[Table of Contents](#)

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

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

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

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

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, in addition to other risks. Foreign regulatory bodies have established varying regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. We may not obtain foreign regulatory approvals on a timely basis, if at all. Foreign regulatory agencies, as well as the FDA, periodically inspect manufacturing facilities both in the U.S. and abroad. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. While we are currently attempting to obtain a CE Mark in Europe, we may not be successful in doing so. Our inability or failure to comply with varying foreign regulations, or the imposition of new regulations, could restrict our sale of products internationally.

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

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

[Table of Contents](#)

Competition for senior management personnel, as well as scientists, clinicians, engineers, and experienced sales and marketing individuals, is intense, and we may not be able to retain our personnel. The loss of the services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the development and introduction of MelaFind®. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement. Each of our officers may terminate their employment at any time without notice and without cause or good reason.

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

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

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

Climate control policy changes, including legislation pending in the U.S. Congress 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 is enacted or treaties ratified, our operations or the operations of our suppliers could be adversely impacted affecting our ability to successfully launch MelaFind® in the U.S. marketplace.

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

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

Risks Relating to our Common Stock

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

[Table of Contents](#)

The Sarbanes-Oxley Act of 2002 (“SOX”), as well as rules subsequently implemented by the SEC, the Public Company Accounting Oversight Board and the NASDAQ Capital Market, have required changes in the corporate governance practices of public companies. Monitoring compliance with the existing rules and implementing changes required by new rules may increase our legal and financial compliance costs, divert management attention from operations and strategic opportunities, and make legal, accounting and administrative activities more time-consuming and costly. On each of June 30, 2007, 2008 and 2009, our market capitalization exceeded \$75 million. As a result we had our independent registered public accounting firm attest to our compliance with Section 404 of SOX as of December 31, 2007, 2008 and 2009. Since 2007, we have retained a consultant experienced in SOX that assists us in the process of instituting changes to our internal procedures to satisfy the requirements of the SOX. We have evaluated our internal control systems in order to allow us to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the SOX. As a small company with limited capital and human resources, going forward we may need to divert management’s time and attention away from our business in order to ensure continued compliance with these regulatory requirements. We may require new information technologies systems, the auditing of our internal controls, and compliance training for our directors, officers and personnel. Such efforts may entail a significant expense. If we fail to maintain the adequacy of our internal controls as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the SOX. Any failure to maintain the adequacy of our internal controls could have an adverse effect on timely and accurate financial reporting and the trading price of our common stock.

An active trading market for our common stock may not be sustained.

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

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

Our stock price is likely to be volatile. Between October 28, 2005 (the date of our initial public offering) and April 30, 2010, our stock price has ranged from \$2.29 to \$12.24 per share. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:

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

[Table of Contents](#)

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

A decline in the market price of our common stock could cause you to lose some or all of your investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders may 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 amended and 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;

Table of Contents

- 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,

[Table of Contents](#)

which may include, among other things, working capital, acquisition or investments in our businesses 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 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 45,000,000 shares of common stock, \$0.001 par value per share. As of April 30, 2010, there were 23,026,035 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.

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 initial public offering in October 2005, we issued 150,000 warrants to the underwriters to purchase shares of our common stock at \$6.25 per share. These 5-year warrants became exercisable on October 28, 2006, and 68,125 remain outstanding at April 30, 2010.

In connection with our November 2006 and August 2007 private placements, we issued warrants to purchase up to 346,857 and 500,041 shares of our common stock, respectively. At April 30, 2010, none of the November 2006 warrants and 346,781 of the August 2007 warrants were outstanding. The August 2007 outstanding warrants are exercisable for five years at a price of \$8.00 per share.

In connection with our May 2009 financing with Kingsbridge Capital, 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 200,000 warrants are outstanding at April 30, 2010.

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, Golenbock Eiseman Assor Bell & Peskoe LLP, New York, New York 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, 2009 have been audited by Eisner 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, 2009 (including information specifically incorporated by reference into our Form 10-K from our Proxy Statement for our 2010 Annual Meeting of Stockholders);
- our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2010;
- our Current Reports on Forms 8-K filed on January 11, 2010, March 24, 2010, April 30, 2010 and May 26, 2010; 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.

6,100,000 Shares



Common Stock

PROSPECTUS SUPPLEMENT

Cowen and Company

February 12, 2013
