

PROSPECTUS

# MELA SCIENCES, INC.

## 21,637,429 Shares

### Common Stock

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This prospectus relates to the resale of up to 21,637,429 shares of our common stock by the selling stockholders named herein. On July 21, 2014, we entered into a securities purchase agreement with the investors identified therein (together, the “Purchasers”), pursuant to which we sold to the Purchasers 12,300 shares of our Series B Convertible Preferred Stock, par value \$0.10 and a stated value of \$1,000 per share (the “Series B Preferred Stock”), convertible into 4,795,321 shares of common stock based upon an initial conversion price of \$2.565, an aggregate of \$15,000,004.60 of 4% senior secured convertible debentures (the “Debentures”), convertible into 5,847,955 shares of common stock based upon an initial conversion price of \$2.565, and warrants to purchase up to 10,643,276 shares of common stock at an exercise price of \$2.45 per share. As part of the transaction described above, we issued to affiliates of H.C. Wainwright & Co., LLC (“H.C. Wainwright”), as compensation for acting as the placement agent for the transaction, warrants to purchase up to 350,877 shares of common stock at an exercise price of \$2.45 per share. To the extent that one or more Purchasers elects to convert their Debentures or respective shares of Series B Preferred Stock and/or one or more Purchasers or H.C. Wainwright elects to exercise their respective warrants to acquire shares of our common stock, this prospectus may be used by the selling stockholders named under the section titled “Selling Stockholders” to resell their shares. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by any selling stockholder, however, we will receive proceeds upon exercise of the warrants.

The selling stockholders may sell their respective shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may resell their respective shares of our common stock in the section titled “Plan of Distribution” beginning on page 23. Each selling stockholder is an “underwriter” within the meaning of the Securities Act of 1933, as amended, with respect to any shares resold under this prospectus by such selling stockholder. Although we will pay the expenses incurred in registering the shares, we will not be paying any underwriting discounts or commissions in connection with the resale of the shares.

Our common stock is listed on the NASDAQ Capital Market under the symbol “MELA.” On October 17, 2014, the last reported sale price of our common stock, as reported on the NASDAQ Capital Market, was \$1.81 per share.

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**Investing in our securities involves a high degree of risk. We refer you to “[Risk Factors](#),” beginning on page 3, as well as the risks discussed under the caption “Risk Factors” in the 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 determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

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The date of this prospectus is October 20, 2014

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

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

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. This prospectus may only be used where it is legal to sell these securities. The information in this prospectus is accurate as of the date on the front cover. You should not assume that the information contained in this prospectus is accurate as of any other date.

This prospectus does not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus in any jurisdiction to or from any person to whom or from whom it is unlawful to make an offer or solicitation of an offer in that jurisdiction.

## PROSPECTUS SUMMARY

*This summary highlights certain information appearing elsewhere in this 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 securities. 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, especially the section 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 technology company dedicated to designing and developing innovative software-driven technology for the clinical early detection and prevention of skin cancer. We primarily focus on the commercialization of our flagship product, the MelaFind® system, and the further design and development of MelaFind® and its technology. The MelaFind® system is an optical diagnostic device that assists dermatologists in the diagnosis of melanoma. It features a hand-held component that uses light of differing wavelengths to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated classification algorithms that have been ‘trained’ and blind tested on our proprietary database of melanomas and benign lesions. The MelaFind® system then provides images and objective data on the relative disorganization of a lesion’s structure that provides substantial additional perspective to assist physicians in the clinical management decision for atypical pigmented skin lesions, including information useful in the decision whether to biopsy the lesion.

In November 2011, we received written approval from the U.S. Food and Drug Administration (“FDA”) for the MelaFind® Pre-Market Approval (“PMA”) application and in September 2011 we received Conformite Europeenne (“CE”) Mark approval. In March 2012, we installed the first commercial MelaFind® systems, and proceeded with the commercial launch of MelaFind®. We are currently conducting a Post-Approval Study or (“PAS”) evaluating the sensitivity and false positive rate of physicians after using the MelaFind® system with their performance if MelaFind® was not available.

The launch of MelaFind® in 2012 and the subsequent commercialization activities supporting the launch did not meet our initial goals and objectives. Revenues were lower than forecasted and expenses continued to increase throughout 2012 and into 2013. In the third quarter of 2013, a significant cost reduction program was put into place. In November 2013, we adopted a refocused “Go-to-Market” strategy concentrating on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma. We also changed our business model for the MelaFind® system from a rental-based to a sales-based model. We have reduced costs, added more experience to our management team, and reorganized our sales and marketing activities.

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

In July 2014, we announced that we took the first step in the process of obtaining insurance reimbursement for our Multi-Spectral Digital Skin Lesion Analysis (“MSDSL”) procedure that is performed by dermatologists utilizing the MelaFind® system as an aid in the detection of melanoma. We submitted an application for a Current Procedural Terminology (“CPT”) code, which is necessary for Medicare Part B reimbursement by the Centers for Medicare and Medicaid Services (“CMS”). Currently, there is no CPT code available for the MelaFind® process. We plan to commence efforts to obtain reimbursement from private insurers during the CMS’ coverage determination process, which is expected to take at least 18 months.

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

We are committed to enhancing the capabilities of the MelaFind® system. Based on the insights from our key opinion leaders and feedback from our users, we are transitioning MelaFind® from a melanoma scoring technology to a dermal imaging and metrics clinical tool. We are also considering the broadening of our target market beyond clinical dermatologists. Our long-term goal is to be an information exchange company, with a focus on optically gathering data that can improve the diagnosis of various cancers, enable better patient care, improve efficiency and reduce costs. The scope and the speed of the implementation of these new strategies will depend on our financial and human resources and ultimately the acceptance of our products in the marketplace.

Our PAS is evaluating the sensitivity and physician's rate of false positive readings after using the MelaFind® system. On October 17, 2013, the FDA notified us that our report with respect to the PAS was inadequate to allow the agency to complete its review, and as a result the FDA revised the PAS status on its website to "Progress Inadequate." In January 2014, a revised enrollment plan and schedule was approved by the FDA and the interactive review process was closed. On April 2, 2014, the FDA updated the study status to "Progress Adequate" and approved our new study timeline. We currently target submission of the PAS report to the FDA by year-end 2018.

We have had net losses for the year ended December 31, 2013 and the six months ended June 30, 2014 of approximately \$25.9 million and \$7.4 million, respectively. We believe, even with cash and cash equivalents held at June 30, 2014, including the cash raised in a private placement in July 2014, that there is significant doubt about our ability to continue as a going concern. We continue to assess the effects of our previously announced cost reduction plan and are prepared to reduce various operational costs. Should we experience unforeseen expenses, or if anticipated revenues are not realized, the effect could have a further negative impact on management's estimated operating results over the next twelve months.

### **Recent Developments**

On July 24, 2014, pursuant to a securities purchase agreement, dated as of July 21, 2014, with the investors identified therein (together, the "Purchasers"), we sold (i) an aggregate of 12,300 shares of Series B Convertible Preferred Stock, par value \$0.10 and a stated value of \$1,000 per share (the "Series B Preferred Stock"), convertible into 4,795,321 shares of common stock at an initial conversion price of \$2.565, (ii) an aggregate of \$15,000,004.60 of 4% senior secured convertible Debentures (the "Debentures"), convertible into 5,847,955 shares of common stock based upon an initial conversion price of \$2.565, (iii) Series A Common Stock Warrants to purchase up to 5,847,955 shares of our common stock (the "Series A Common Stock Warrants") and (iv) Series B Common Stock Warrants to purchase up to an aggregate of 4,795,321 shares of our common stock (the "Series B Common Stock Warrants", and together with the Series A Common Stock Warrants, the "Warrants") for aggregate gross proceeds of \$27.3 million. We refer to this as the Series B Financing. Simultaneously with the closing of the Series B Financing, we used a portion of the gross proceeds to redeem 12,300 shares of our Series A Preferred Stock for an aggregate amount of \$12.3 million. See "Selling Stockholders – Relationships with Selling Stockholders."

The Series A Common Stock Warrants have an exercise price of \$2.45 per share, are immediately exercisable and have a term of five years. The Series B Common Stock Warrants have an exercise price of \$2.45 per share, are immediately exercisable and have a term of eighteen months. The number of shares issuable upon conversion of the Series B Preferred Stock and exercise of the Warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar transactions. In connection with the financing, the Purchasers have been granted rights of participation in future offerings of our securities for a period of eighteen (18) months. As part of the Series B Financing, we issued to affiliates of H.C. Wainwright & Co., LLC ("H.C. Wainwright"), as compensation for acting as the placement agent for the transaction, Series A Common Stock Warrants to purchase up to 350,877 shares of common stock.

The Debentures described above bear interest at an annual rate of 4%, payable quarterly or upon conversion into shares of common stock registered under the Securities Act. Our obligations under the Debentures are secured by a first priority lien on all of our intellectual property pursuant to the terms of a security agreement ("Security Agreement"), dated July 21, 2014 among us and the Purchasers.

In connection with the Series B Financing, we also granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Series B Preferred Stock, the Debentures and the Warrants pursuant to the terms of a Registration Rights Agreement. In addition to the registration rights, the Purchasers are entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, getting effective and maintaining an effective registration statement covering the shares underlying the Series B Preferred Stock and the Warrants, including a failure to file a resale registration statement by no later than August 20, 2014, and a failure to have such resale registration statement declared effective by the Securities and Exchange Commission (the "SEC") by no later than October 19, 2014. The liquidated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquidated damages payable is equal to 2.0% of the aggregate purchase price paid by each Purchaser, provided, however, the maximum aggregate liquidated damages payable to a Purchaser shall be 12% of the aggregate subscription amount paid by such Purchaser pursuant to the Purchase Agreement. The liquidated damages shall accrue interest at a rate of 12% per annum (or such lesser maximum amount that is permitted to be paid by applicable law), accruing on a daily basis for each event until such event is cured.

The Registration Rights Agreement requires us to file this registration statement for all of the securities that may be issued upon conversion of the Series B Preferred Stock and the Debentures and exercise of the warrants issued to the Purchasers. Pursuant to the applicable transaction documents, however, no Purchaser may exercise its conversion/exercise rights for that number of shares of common stock which, together with all other shares owned by it and its affiliates would result in more than 9.99% of our issued and outstanding shares of common stock calculated on the basis of the then outstanding shares. Regardless of this limitation, assuming all of the shares of common stock registered for resale are issued, on an after issued basis, they will represent 80.6% of the then issued and outstanding shares of common stock based on 5,213,969 shares of common stock outstanding as of August 15, 2014.

### **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](http://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. Before buying any of the securities offered by the selling stockholders, you should carefully consider the risk factors below, 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, 2013, 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. 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 the securities offered by the selling stockholders.*

### **Risks Relating to the Private Placement Transaction**

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

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

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

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

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

### **Risks Relating to Our Business**

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

Since 1999, we have primarily financed our operations through the sale of our equity securities and have devoted substantially all of our resources to research, development and commercialization of the MelaFind® system. Our net income/(loss) for the three and six months ended June 30, 2014 was approximately \$0.6 million and (\$7.4 million), respectively, and as of June 30, 2014, we had an

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accumulated deficit of approximately \$175.5 million. Our expenses will increase in connection with our continued commercialization and development activities related to MelaFind®. Having commenced commercialization in March 2012, we expect to incur additional medical, marketing and sales expenses in the near future and to incur additional contract manufacturing and inventory expenses in the future which will require additional funding. Furthermore, having recently commenced a refocused marketing strategy focusing on key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma, we expect to incur additional expenses continuing to transition our operations and implementing our refocused marketing strategy. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future and cannot determine at this time when we will generate any significant revenues. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.***

The report of our independent auditors dated March 17, 2014 on our consolidated financial statements for the period ended December 31, 2013 included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Our auditors' doubts are based on our inability to establish an ongoing source of revenue sufficient to cover our operating costs and recurring losses from operations. Our ability to continue as a going concern will be determined by our ability to generate sufficient cash flow to sustain our operations and/or raise additional capital in the form of debt or equity financing. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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

As of June 30, 2014, we had approximately \$4.2 million in cash and cash equivalents, which does not include \$14.0 million in net proceeds that we received in our recently completed private placement of Series B Preferred Stock, Debentures and Warrants, and cash used in operations for the six months ended June 30, 2014 was approximately \$11.0 million. Our total liabilities at June 30, 2014 were approximately \$5.3 million. We expect to incur significant losses for the foreseeable future and may not achieve operating profits or positive cash flows from operations. Furthermore, under the terms of our recently completed private placement of our Series B Preferred Stock, Debentures and Warrants, we are prohibited from selling any (i) shares of our common stock or securities convertible into shares of common stock until ninety (90) days after the registration statement, of which this prospectus forms a part, is declared effective by the SEC or (ii) effecting or entering into an agreement to effect any issuance of common stock or securities convertible into shares of common stock (or a combination of units thereof) involving a variable rate transaction until twelve (12) months after the registration statement, of which this prospectus forms a part, is declared effective by the SEC. Our ability to fund our operations is not assured and will be impacted by market acceptance of MelaFind®, cost cutting measures that are in place currently or may be put into place in the future and our ability to raise capital. We anticipate that long-term we will need to raise additional funds to broaden the commercialization and awareness of MelaFind®, including implementing our refocused marketing strategy focusing on the key institutions, opinion leaders and dermatologists who treat many of the patients at high risk for melanoma. The timing and amount of any additional funding we may require will be affected by the commercial success of our MelaFind® product. The amount of funding we will need will depend on many factors, including:

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

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

***We may have to pay liquidated damages of \$3.3 million to the investors in our recent financing of Series B Preferred Stock, Debentures and Warrants.***

In July 2014, we sold an aggregate of 12,300 shares of our Series B Preferred Stock, convertible into 4,795,321 shares of our common stock at an initial conversion price of \$2.565, \$15.0 million of Debentures, convertible into 5,847,955 shares of our common stock at an initial conversion price of \$2.565, and Series A Common Stock Warrants to purchase up to 5,847,955 shares of our common stock and Series B Common Stock Warrants to purchase up to 4,795,321 shares of our common stock, for aggregate gross proceeds of \$27.3 million to certain institutional investors (the "Purchasers"). In connection with this financing, we granted to the Purchasers resale registration rights with respect to the shares of common stock underlying the Series B Preferred Stock, the Debentures and the Warrants pursuant to the terms of a Registration Rights Agreement. In addition to the registration rights, the Purchasers are entitled to receive liquidated damages upon the occurrence of a number of events relating to filing, getting effective and maintaining an effective registration statement covering the shares underlying the Series B Preferred Stock, the Debentures and the warrants, including a failure to file a resale registration statement by no later than August 20, 2014, and a failure to have such resale registration statement declared effective by the SEC by no later than October 19, 2014. The liquidated damages will be payable upon the occurrence of each of those events and each monthly anniversary thereof until cured. The amount of liquidated damages payable upon each event and the monthly anniversary of such event is equal to 2.0% of the aggregate purchase price paid by each Purchaser, provided, however, the maximum aggregate liquidated damages payable to a Purchaser shall be 12% of the aggregate subscription amount paid by such Purchaser pursuant to the Purchase Agreement. The liquidated damages shall accrue interest at a rate of 12% per annum (or such lesser amount that is permitted to be paid by applicable law), accruing on a daily basis for each event until such event is cured.

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

The success of MelaFind® will depend upon the level of acceptance by dermatologists who perform skin examinations and treat patients who are at high risk for melanoma that the evaluation information provided by MelaFind® is medically useful and reliable. We will be subject to intense scrutiny before physicians will be comfortable incorporating MelaFind® in their diagnostic approaches. We believe that recommendations by respected physicians will be essential for the development and successful marketing of MelaFind®; however, there can be no assurance that a significant number of such recommendations will be obtained. To date, the medical community outside of our customer base has had little exposure to us and MelaFind®. The medical community is often skeptical of new companies and new technologies, thus, we may be unable to gain access to potential customers in order to demonstrate the operation and effectiveness of MelaFind®. Even if we gain access to potential customers, no assurance can be given that members of the dermatological medical community will perceive a need for or accept MelaFind®. This challenge is not new to the diagnostic device industry as many devices suffer the same initial market reluctance, as integrating new diagnostic tools present a challenge of adaption that many physicians are not active in overcoming. As such, physicians who are trained to trust their clinical diagnostic accuracy may not see the need to add diagnostic tools to their already established clinical management process. Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind® by the dermatological community. Insufficient market acceptance of MelaFind® would have a material adverse effect on our business, financial condition and results of operations.

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

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

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



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

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

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

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

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

We are required to submit to the FDA progress reports on this study every six months during the first two years and annually thereafter. The first progress report was submitted to the FDA in February 2013, the second was submitted on August 8, 2013 and the third report was submitted on February 7, 2014. If the FDA has questions on the data provided in a progress report, or believes the data are incomplete or insufficient, the agency may request additional information, including through a deficiency letter. For example, on March 4, 2013 and October 17, 2013, the FDA sent a letter stating that the information in our progress report was inadequate to allow the agency to complete its review and therefore the FDA asked for additional information. We responded to the March 4, 2013 letter on March 22, 2013 and the October 17, 2013 letter on November 15, 2013. We placed the study on hold September 9, 2013 to investigate below expected enrollment numbers. An interactive review process was initiated by the FDA on January 2, 2014, requesting additional information beyond our October 17, 2013 response letter to the FDA. On January 13, 2014, the FDA closed the interactive review process, deeming that we have sufficiently met our reporting obligations. The study was restarted on February 25, 2014 and on April 2, 2014 the FDA approved our new study timeline and listed our study status as Progress Adequate. On August 8, 2014, we submitted our two year progress report to FDA with revised study timelines, extending all milestones by one year and we are awaiting FDA response. The FDA may seek the advice of advisory panels of outside experts when considering the initiation or progress of post-approval studies. If we have not met the study milestones or timeline specified in the study protocol, we must provide a rationale to the FDA in our progress reports. If a change in the study milestones or timeline could significantly affect the outcome of the PAS, we will need to submit that revision for the agency's review and approval. We will need to update MelaFind®'s labeling with the results from this study, including any positive or negative results.

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

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

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The FDA posts information about the status of post-approval studies on its website. These website postings could undermine our credibility or that of MelaFind®, or have other collateral effects. For example, the agency will identify the study status as “Progress Inadequate” if the study progress is inconsistent with the protocol, such as if the study is not meeting the enrollment schedule or study timeline, missing time point evaluations, if there are poor follow-up rates, or if not all the endpoints are evaluated. Because of rate of accrual issues, the FDA’s October 17, 2013 letter informed us that our study status was revised on the FDA’s website to “Progress Inadequate.” On January 13, 2014, while closing our interactive review process, the FDA informed us that the “Progress Inadequate” status would not be revised until the study hold is removed. Our new study timeline was approved for study restart in January 2014 and the study status was updated to “Progress Adequate” on April 2, 2014, following a February 25, 2014 study restart.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

While several companies including Verisante, Scibase and Caliber Imaging and Diagnostic, Inc. (formerly Lucid, Inc.) have technologies that may be used to assist the dermatologist none of these companies' products have undergone the rigors of FDA PMA review and subsequent approval. We believe that other products that enhance the visualization and analysis of potential melanomas have been approved or are under development by: Welch Allyn, Inc.; Heine Optotechnik; 3Gen, LLC; Derma Medical Systems, Inc.; MedX Health; Biomips Engineering, Michelson Diagnostics, Riester, ViseoMed, AG and others. In addition, several companies have developed various dermatological apps for use with an Apple iPhone. The broader market for precision optical imaging devices used for medical diagnosis is intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. We will potentially be subject to competition from major optical imaging companies, such as: Raytheon Corporation, General Electric Co.; Siemens AG; Bayer AG; Olympus Corporation; Carl Zeiss AG Deutschland; and others, each of which manufactures and markets precision optical imaging products for the medical market, and could decide to develop or acquire a product to compete with MelaFind®. These companies enjoy numerous competitive advantages, including:

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

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

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

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

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

We have limited experience in manufacturing MelaFind® for commercial distribution and are using a contract manufacturer to produce our units. When we enter into contracts for the third-party manufacture of our devices, the quality of the devices will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Manufacturers often encounter

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difficulties in scaling up production of new products, including problems involving product yields, controlling and anticipating product costs, quality control and assurance, component supply, and shortages of qualified personnel. We cannot assure you that the third-party contract manufacturers with whom we have developed or are developing relationships will have or sustain the ability to produce the quantities of MelaFind® needed for development or commercial sales at prices that allow MelaFind® to compete successfully in the market.

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

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

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

- suppliers may make errors in manufacturing components that could negatively impact the effectiveness or safety of our products, or cause delays in shipment of our products;
- we may have difficulty locating and qualifying alternative suppliers for our sole-source suppliers;
- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from

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knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs and; the Civil Monetary Penalties Law, which authorizes HHS to impose civil penalties administratively for fraudulent or abusive acts. Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use of MelaFind® by physicians may dissuade physicians from either purchasing or using MelaFind® and could have a material adverse effect on our ability to successfully commercialize MelaFind®.

### ***The application of the privacy provisions of HIPAA is uncertain.***

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

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

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

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

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

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



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

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

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

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

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

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

***We may be adversely affected by a data center failure.***

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

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

In October 2013, we entered into a securities purchase agreement pursuant to which we issued Series A and Series B warrants to purchase up to 0.7 and 0.4 million shares of our common stock, respectively, and in January 2014, we entered into a securities purchase agreement pursuant to which we issued warrants to purchase up to 1.3 million shares of our common stock. The Series A warrants from October 2013 and all of the January 2014 warrants have been recorded at their respective fair values at the inception date of the respective agreement under which they were issued, and will be recorded at their respective fair values at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on our financial results. The fair value of the warrants is tied in large part to our stock price. If our stock price increases between reporting periods, the warrants become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

***We may be adversely affected by breaches of online security.***

Our MelaFind® lesion database does not contain any information that allows us to identify specific patients. However, we must identify certain data as belonging to or as derived from specific patients for regulatory, quality assurance and billing purposes. To the extent that our activities involve the storage and transmission of confidential information, security breaches could damage our

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

### ***We are dependent upon telecommunications and the internet.***

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

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

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

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

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

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

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

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

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

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

### ***Regulations related to conflict minerals may adversely affect us.***

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

## **Risks Relating to our Common Stock**

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

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

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

Currently, our common stock trades on the NASDAQ Capital Market. Previously, we received notifications from the NASDAQ informing us of certain listing deficiencies related to the minimum bid price listing requirements. Although we have since cured these deficiencies, it is possible that we could fall out of compliance again in the future. If we fail to maintain compliance with any NASDAQ listing requirements, we could be delisted. If that were to occur, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and security analysts’ coverage of us may be reduced. Furthermore, while we believe that our common stock would trade on the OTC Bulletin Board, we would lose various advantages attendant to listing on a national securities exchange, including but not limited to, eligibility to register the sale or resale of our shares on Form S-3 and the automatic exemption from registration under state securities laws for exchange listed securities, which could have a negative effect on our ability to raise funds.

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

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

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

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

- failure of any of our products to achieve commercial success;
- the timing of regulatory approval for our future products;
- results of our research and development efforts and our clinical trials;

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

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

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

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

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

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

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

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

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

## **USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of the securities by the selling stockholders. To the extent proceeds are received upon exercise of the warrants, we intend to use any such proceeds for general corporate and working capital purposes.

## SELLING STOCKHOLDERS

This prospectus relates to the possible resale by the selling stockholders of shares of common stock that we may issue upon conversion of our Series B Preferred Stock, the Debentures or upon exercise of warrants that we issued to the selling stockholders. We are filing the registration statement, of which this prospectus forms a part, and registering the shares of common stock pursuant to the provisions of the Registration Rights Agreement we entered into with the Purchasers on July 21, 2014 and an engagement letter that we entered into with H.C. Wainwright & Co., LLC on June 13, 2014. Each selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares of common stock that it acquires upon conversion of its respective shares of Series B Preferred Stock or upon exercise of its respective warrants.

The following table presents information regarding the selling stockholders, and the shares of common stock that they may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholders. As used in this prospectus, the term “selling stockholder” includes any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column “Number of Shares Being Offered” represents all of the shares that the selling stockholders may offer under this prospectus. The selling stockholders may sell some, all or none of its respective shares of common stock. We do not know how long any selling stockholder will hold their respective shares before selling them, and we currently have no agreements, arrangements or understandings with any selling stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares of common stock beneficially owned after the offering shown in the table below is based on an aggregate of 5,213,969 shares of our common stock outstanding on October 1, 2014.

Selling Stockholder	Shares Beneficially Owned Prior to the Offering	Number of Shares Being Offered <sup>(1)</sup>	Shares Beneficially Owned After the Offering	Percentage of Beneficial Ownership After the Offering
Broadfin Healthcare Master Fund, LTD <sup>(2)</sup>	6,087,039	5,654,606 <sup>(3)</sup>	432,433	7.66%
Sabby Healthcare Volatility Master Fund Ltd. <sup>(5)</sup>	10,208,503	9,045,568 <sup>(6)</sup>	1,162,935 <sup>(7)</sup>	9.99%
Sabby Volatility Warrant Master Fund Ltd. <sup>(8)</sup>	3,887,546	3,467,468 <sup>(9)</sup>	420,078 <sup>(10)</sup>	9.99%
Cranshire Capital Master Fund, LTD <sup>(11)</sup>	662,768	662,768 <sup>(12)</sup>	0	*
Equitec Specialists, LLC <sup>(13)</sup>	116,960	116,960 <sup>(14)</sup>	0	*
Biomedical Value Fund, L.P. <sup>(15)</sup>	860,876	860,876 <sup>(16)</sup>	0	*
Biomedical Institutional Value Fund, L.P. <sup>(17)</sup>	190,092	190,092 <sup>(18)</sup>	0	*
Biomedical Offshore Value Fund, Ltd. <sup>(19)</sup>	649,274	649,274 <sup>(20)</sup>	0	*
GEF-SMA, L.P. <sup>(21)</sup>	444,222	444,222 <sup>(22)</sup>	0	*
Class D Series of GEF-PS, L.P. <sup>(23)</sup>	194,718	194,718 <sup>(24)</sup>	0	*
Michael Vasinkevich <sup>(25)</sup>	117,544	117,544 <sup>(26)</sup>	0	*
H.C. Wainwright & Co., LLC <sup>(27)</sup>	105,263	105,263 <sup>(28)</sup>	0	*
Noam Rubinstein <sup>(29)</sup>	114,035	114,035 <sup>(30)</sup>	0	*
Mark Viklund <sup>(31)</sup>	10,526	10,526 <sup>(32)</sup>	0	*
Charles Worthman <sup>(33)</sup>	3,509	3,509 <sup>(34)</sup>	0	*

\* Represents beneficial ownership of less than 1% of the shares of common stock.

- (1) Assumes that all shares of Series B Preferred Stock and Debentures are converted to common stock, and all warrants are exercised, in full without regard to any conversion limitations contained therein.
- (2) The business address of Broadfin Healthcare Master Fund, LTD (“Broadfin”) is 20 Genesis Close Ansbacher House, Second Floor, P.O. Box 1344, Grand Cayman KY1-1108, Cayman Islands and the business address of each of Broadfin Capital, LLC and Kevin Kotler is 237 Park Avenue, 9th Floor, New York, NY 10017. Broadfin, Broadfin Capital, LLC and Kevin Kotler have shared voting and investment control of the securities held by Broadfin.
- (3) Consists of 1,559,454 shares of common stock issuable upon conversion of 4,000 shares of Series B Preferred Stock and Debentures with a principal amount of \$3,252,032.69 convertible into 1,267,849 shares of common stock, 1,267,849 shares of common stock issuable upon exercise of a Series A Common Stock Warrant and 1,559,454 shares of common stock issuable upon exercise of a Series B Common Stock Warrant held by Broadfin. Both the conversion of the Series B Preferred Stock and the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (4) Includes shares of common stock issuable upon exercise of warrants held by Broadfin, which are subject to a 9.99% blocker. This information is based upon a Selling Stockholder Notice and Questionnaire provided by Broadfin on August 13, 2014, as amended.
- (5) The business address of Sabby Healthcare Volatility Master Fund Ltd. (“Sabby HVMF”) is c/o Sabby Management LLC, 10 Mountainview Road, Suite 205, Upper Saddle River, NJ 07458. Sabby Management, LLC serves as the investment manager of Sabby HVMF. Hal Mintz is the manager of Sabby Management, LLC and has voting and investment control of the securities held by Sabby HVMF. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities beneficially owned by Sabby HVMF except to the extent of their respective pecuniary interest therein.

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- (6) Consists of 2,339,181 shares of common stock issuable upon conversion of 6,000 shares of Series B Preferred Stock and Debentures with a principal amount of \$5,600,941.70 convertible into 2,183,603 shares of common stock and 2,183,603 shares of common stock issuable upon exercise of a Series A Common Stock Warrant and 2,339,181 shares of common stock issuable upon exercise of a Series B Common Stock Warrant held by Sabby HVMF. Both the conversion of the Series B Preferred Stock and the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (7) Includes shares of common stock issuable upon exercise of warrants held by Sabby HVMF, which are subject to a 9.99% blocker. This information is based upon a Selling Stockholder Notice and Questionnaire provided by Sabby HVMF on July 25, 2014.
- (8) The business address of Sabby Volatility Warrant Master Fund Ltd. ("Sabby VWMF") is c/o Sabby Management LLC, 10 Mountainview Road, Suite 205, Upper Saddle River, NJ 07458. Sabby Management, LLC serves as the investment manager of Sabby VWMF. Hal Mintz is the manager of Sabby Management, LLC and has voting and investment control of the securities held by Sabby VWMF. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities beneficially owned by Sabby VWMF except to the extent of their respective pecuniary interest therein.
- (9) Consists of 896,686 shares of common stock issuable upon conversion of 2,300 shares of Series B Preferred Stock and Debentures with a principal amount of \$2,147,028.12 convertible into 837,048 shares of common stock and 837,048 shares of common stock issuable upon exercise of a Series A Common Stock Warrant and 896,686 shares of common stock issuable upon exercise of a Series B Common Stock Warrant held by Sabby VWMF. Both the conversion of the Series B Preferred Stock and the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (10) Includes shares of common stock issuable upon exercise of warrants held by Sabby VWMF, which are subject to a 9.99% blocker. This information is based upon a Selling Stockholder Notice and Questionnaire provided by Sabby VWMF on July 25, 2014.
- (11) The business address of Cranshire Capital Master Fund, LTD ("Cranshire") is c/o Cranshire Capital Advisors, LLC, 3100 Dundee Road, Suite 703, Northbrook, IL 60062. Cranshire Capital Advisors, LLC ("CCA") is the investment manager of Cranshire Capital Master Fund, Ltd. ("Cranshire Master Fund") and has voting control and investment discretion over securities held by Cranshire Master Fund. Mitchell P. Kopin ("Mr. Kopin"), the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Cranshire Master Fund. CCA is also the investment manager for managed accounts for Equitec Specialists, LLC ("Equitec") and CCA has voting control and investment discretion over securities held in the managed accounts for Equitec. Mr. Kopin, the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA also may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Equitec that are described in footnotes 13 and 14. Cranshire Master Fund acquired the shares being registered hereunder in the ordinary course of business, and at the time of the acquisition of the shares and warrants described herein, Cranshire Master Fund did not have any arrangements or understandings with any person to distribute such securities.
- (12) Consists of Debentures with a principal amount of \$849,999.96 convertible into 331,384 shares of common stock and 331,384 shares of common stock issuable upon exercise of a Series A Common Stock Warrant. The conversion of the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (13) The business address of Equitec Specialists, LLC ("Equitec") is c/o Cranshire Capital Advisors, LLC, 3100 Dundee Road, Suite 703, Northbrook, IL 60062. CCA is the investment manager of a managed account for Equitec Specialists, LLC ("Equitec") and has voting control and investment discretion over securities held in by Equitec in such managed account, Mr. Kopin, the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Equitec in such managed account. CCA is also the investment manager of Cranshire Capital Master Fund, Ltd. ("Cranshire Master Fund"). Mr. Kopin, the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Cranshire Master Fund that are described in footnotes 11 and 12. Equitec is an affiliate of a broker-dealer. Equitec has certified to us that they acquired the shares being registered hereunder in the ordinary course of business, and at the time of the acquisition of the shares and warrants described herein, Equitec did not have any arrangements or understandings with any person to distribute such securities.

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- (14) Consists of Debentures with a principal amount of \$150,001.20 convertible into 58,480 shares of common stock and 58,480 shares of common stock issuable upon exercise of a Series A Common Stock Warrant. The conversion of the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (15) The business address of Biomedical Value Fund, L.P. (“Biomedical VP”) is c/o Great Point Partners, LLC, 165 Mason Street, 3rd Floor, Greenwich, CT 06830. Great Point Partners, LLC (“Great Point”) serves as the investment manager of Biomedical VP. Jeffrey R. Jay as senior managing member of Great Point and David Kroin as special managing member of Great Point have voting and investment power with respect to the shares and therefore may be deemed to be the beneficial owner of all shares. Each of Great Point, Dr. Jay and Mr. Kroin disclaims beneficial ownership over the securities beneficially owned by Biomedical VP except to the extent of their respective pecuniary interest therein.
- (16) Consists of Debentures with a principal amount of \$1,104,073.47 convertible into 430,438 shares of common stock and 430,438 shares of common stock issuable upon exercise of a Series A Common Stock Warrant. The conversion of the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (17) The business address of Biomedical Institutional Value Fund, L.P. (“Biomedical IVP”) is c/o Great Point Partners, LLC, 165 Mason Street, 3rd Floor, Greenwich, CT 06830. Great Point serves as the investment manager of Biomedical IVP. Jeffrey R. Jay as senior managing member of Great Point and David Kroin as special managing member of Great Point have voting and investment power with respect to the shares and therefore may be deemed to be the beneficial owner of all shares. Each of Great Point, Dr. Jay and Mr. Kroin disclaims beneficial ownership over the securities beneficially owned by Biomedical IVP except to the extent of their respective pecuniary interest therein.
- (18) Consists of Debentures with a principal amount of \$243,792.99 convertible into 95,046 shares of common stock and 95,046 shares of common stock issuable upon exercise of a Series A Common Stock Warrant. The conversion of the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (19) The business address of Biomedical Offshore Value Fund, Ltd. (“Biomedical OVP”) is c/o Great Point Partners, LLC, 165 Mason Street, 3rd Floor, Greenwich, CT 06830. Great Point serves as the investment manager of Biomedical OVP. Jeffrey R. Jay as senior managing member of Great Point and David Kroin as special managing member of Great Point have voting and investment power with respect to the shares and therefore may be deemed to be the beneficial owner of all shares. Each of Great Point, Dr. Jay and Mr. Kroin disclaims beneficial ownership over the securities beneficially owned by Biomedical OVP except to the extent of their respective pecuniary interest therein.
- (20) Consists of Debentures with a principal amount of \$832,693.91 convertible into 324,637 shares of common stock and 324,637 shares of common stock issuable upon exercise of a Series A Common Stock Warrant. The conversion of the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (21) The business address of GEF-SMA, L.P. (“GEF-SMA”) is c/o Great Point Partners, LLC, 165 Mason Street, 3rd Floor, Greenwich, CT 06830. Great Point serves as the investment manager of GEF-SMA. Jeffrey R. Jay as senior managing member of Great Point and David Kroin as special managing member of Great Point have voting and investment power with respect to the shares and therefore may be deemed to be the beneficial owner of all shares. Each of Great Point, Dr. Jay and Mr. Kroin disclaims beneficial ownership over the securities beneficially owned by GEF-SMA except to the extent of their respective pecuniary interest therein.
- (22) Consists of Debentures with a principal amount of \$569,714.72 convertible into 222,111 shares of common stock and 222,111 shares of common stock issuable upon exercise of a Series A Common Stock Warrant. The conversion of the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (23) The business address of Class D Series of GEF-PS, L.P. (“GEF-PS”) is c/o Great Point Partners, LLC, 165 Mason Street, 3rd Floor, Greenwich, CT 06830. Great Point serves as the investment manager of GEF-PS. Jeffrey R. Jay as senior managing member of Great Point and David Kroin as special managing member of Great Point have voting and investment power with respect to the shares and therefore may be deemed to be the beneficial owner of all shares. Each of Great Point, Dr. Jay and Mr. Kroin disclaims beneficial ownership over the securities beneficially owned by GEF-PS except to the extent of their respective pecuniary interest therein.
- (24) Consists of Debentures with a principal amount of \$249,725.84 convertible into 97,359 shares of common stock and 97,359 shares of common stock issuable upon exercise of a Series A Common Stock Warrant. The conversion of the Debentures and the exercise of the warrants are subject to a 9.99% blocker.
- (25) The address of Michael Vasinkevich is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022. Mr. Vasinkevich acquired shares being registered hereunder in connection with H.C. Wainwright serving as the placement agent in the Series B Financing and he was not an investor in the Series B Financing. Mr. Vasinkevich is an affiliate of a broker-dealer and has certified to us that he acquired the shares being offered by him in the ordinary course of business, and, at the time he acquired the shares being registered hereunder, he had no agreements or understandings, directly or indirectly, with any person to distribute the shares being offered by him.
- (26) Consists of shares of common stock issuable upon exercise of a Series A Common Stock Warrant held by Michael Vasinkevich.



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- (27) The business address of H.C. Wainwright & Co., LLC (“H.C. Wainwright”) is 430 Park Avenue, New York, New York 10022. H.C. Wainwright has indicated that it is a registered broker-dealer. H.C. Wainwright acquired the shares being registered hereunder as compensation for serving as the placement agent in the Series B Financing and was not an investor in the Series B Financing.
- (28) Consists of shares of common stock issuable upon exercise of a Series A Common Stock Warrant held by H.C. Wainwright & Co., LLC.
- (29) The address of Noam Rubinstein is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022. Mr. Rubinstein acquired shares being registered hereunder in connection with H.C. Wainwright serving as the placement agent in the Series B Financing and he was not an investor in the Series B Financing. Mr. Rubinstein is an affiliate of a broker-dealer and has certified to us that he acquired the shares being offered by him in the ordinary course of business, and, at the time he acquired the shares being registered hereunder, he had no agreements or understandings, directly or indirectly, with any person to distribute the shares being offered by him.
- (30) Consists of shares of common stock issuable upon exercise of a Series A Common Stock Warrant held by Noam Rubinstein.
- (31) The address of Mark Viklund is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022. Mr. Viklund acquired shares being registered hereunder in connection with H.C. Wainwright serving as the placement agent in the Series B Financing and he was not an investor in the Series B Financing. Mr. Viklund is an affiliate of a broker-dealer and has certified to us that he acquired the shares being offered by him in the ordinary course of business, and, at the time he acquired the shares being registered hereunder, he had no agreements or understandings, directly or indirectly, with any person to distribute the shares being offered by him.
- (32) Consists of shares of common stock issuable upon exercise of a Series A Common Stock Warrant held by Mark Viklund.
- (33) The address of Charles Worthman is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022. Mr. Worthman acquired shares being registered hereunder in connection with H.C. Wainwright serving as the placement agent in the Series B Financing and he was not an investor in the Series B Financing. Mr. Worthman is an affiliate of a broker-dealer and has certified to us that he acquired the shares being offered by him in the ordinary course of business, and, at the time he acquired the shares being registered hereunder, he had no agreements or understandings, directly or indirectly, with any person to distribute the shares being offered by him.
- (34) Consists of shares of common stock issuable upon exercise of a Series A Common Stock Warrant held by Charles Worthman.

### **Relationships with Selling Stockholders**

In February 2014, we sold to Broadfin for \$4.0 million (i) 4,000 shares of Series A Convertible Preferred Stock (the “Series A Preferred Stock”) at a price per share of \$1,000, convertible into 476,191 shares of common stock at a conversion price of \$8.40, and (ii) warrants to purchase up to 432,433 shares of the Company’s common stock. At the same time, we sold to Sabby HVMF and Sabby VWMF for \$8.3 million (i) an aggregate of 8,300 shares of Series A Preferred Stock at a price per share of \$1,000, convertible into 988,095 shares of common stock at an initial conversion price of \$8.40 and (ii) warrants to purchase up to 897,297 shares of the Company’s common stock. We refer to this as the Series A Financing. The warrants have an exercise price of \$7.40 per share, are immediately exercisable and have a term of five years. We received net proceeds of approximately \$11.4 million in this offering.

On January 31, 2014, as part of the Series A Financing, we entered into an agreement granting to Broadfin the right to designate one director to our Board of Directors, so as long as it retained 30% of its investment in the Series A Preferred Stock (or the shares of common stock underlying the Preferred Stock) or held any warrants. Samuel Navarro, Managing Partner at Gravitas Healthcare, LLC, a firm which provides strategic advisory services to medical technology companies, was appointed to serve on our Board of Directors in March 2014 pursuant to this designation right. On March 31, 2014, we and Broadfin agreed to terminate this designation right. Notwithstanding this termination, our Board of Directors determined that having Mr. Navarro on the Board would be in our best interests and those of our stockholders, and therefore decided to include Mr. Navarro on the slate of directors to be nominated for election at the 2014 annual meeting of stockholders.

In connection with the Series B Financing, we redeemed all 12,300 shares of Series A Preferred Stock from Broadfin, Sabby HVMF and Sabby VWMF at \$1,000 per share for an aggregate amount of \$12.3 million. All of the warrants issued in the Series A Financing continue to remain outstanding.

## PLAN OF DISTRIBUTION

Each Selling Stockholder (the “Selling Stockholders”) of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq Stock Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 under the Securities Act of 1933, as amended (the “Securities Act”), if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with the Financial Industry Regulatory Authority (“FINRA”) Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that, at the time it acquired the securities being sold hereunder, it acquired the securities in the ordinary course of business and it did not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be “underwriters” within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The Selling Stockholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the resale securities by the Selling Stockholders.

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We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

### **LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts.

### **EXPERTS**

The financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K, for the year ended December 31, 2013 have been audited by EisnerAmper LLP, an independent registered public accounting firm as stated in their report incorporated herein by reference, which report has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

### **WHERE YOU CAN FIND MORE INFORMATION**

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

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

### **INCORPORATION OF CERTAIN DOCUMENTS 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, 2013, as amended, filed with the SEC on March 17, 2014, as amended April 2, 2014;

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- the portions of our Definitive Proxy Statement on Schedule 14A that are deemed “filed” with the SEC under the Securities Exchange Act of 1934, as amended, filed with the SEC on April 14, 2014;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014 and June 30, 2014, filed with the SEC on May 14, 2014 and August 14, 2014, respectively;
- our Current Reports on Form 8-K filed on January 6, 2014, February 3, 2014, February 21, 2014, March 17, 2014 and April 1, 2014 (as amended April 2, 2014), April 9, 2014, May 16, 2014, July 10, 2014, July 23, 2014, July 29, 2014 and August 6, 2014; and
- the description of our common stock contained in our registration statement on Form 8-A, filed with the SEC on August 8, 2005, 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.

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: Rose Crane  
(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.**

21,637,429 Shares



Common Stock

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PROSPECTUS

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October 20, 2014

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