



PROSPECTUS

# ELECTRO-OPTICAL SCIENCES, INC.

3,527,000 Shares

Common Stock

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This prospectus relates to the resale of up to 3,527,000 shares of our common stock by the selling stockholder named herein. On May 7, 2009, we entered into a common stock purchase agreement with Kingsbridge Capital Limited, or Kingsbridge, pursuant to which we may, in our sole discretion with no obligation to do so, sell to Kingsbridge up to 3,327,000 shares of our common stock. On the same date, we issued Kingsbridge a warrant to purchase up to 200,000 shares of our common stock. To the extent that we elect to sell any shares of our common stock to Kingsbridge pursuant to the common stock purchase agreement or Kingsbridge elects to exercise the warrant to acquire shares, this prospectus may be used by the selling stockholder named under the section titled "Selling Stockholder" to resell such shares. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder, however, we will receive the proceeds of the shares sold under the common stock purchase agreement or under the warrant on its exercise.

The selling stockholder may sell the 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 stockholder may resell its shares of our common stock in the section titled "Plan of Distribution" beginning on page 27. Kingsbridge is an "underwriter" within the meaning of the Securities Act of 1933 with respect to any shares resold under this prospectus by the selling stockholder. Although we will pay the expenses incurred in registering the shares, we will not be paying any underwriting discounts or commissions in this offering.

Our common stock is listed on the NASDAQ Capital Market under the symbol "MELA." On May 21, 2009, the last reported sale price of our common stock, as reported in the NASDAQ Capital Market, was \$8.21 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 6, as well as the risks discussed under the caption "Risk Factors" in the documents we subsequently file with the Securities and Exchange Commission.**

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**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 May 22, 2009

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*In this prospectus, references to “EOS,” the “Company,” “we,” “our” or “us,” unless the context otherwise requires, refer to Electro-Optical Sciences, Inc.*

*This prospectus contains references to our U.S. registered trademarks: MelaFind® and the corporate logo for “eos — electro-optical sciences, inc.®” All other trademarks, tradenames and service marks appearing in this prospectus are the property of their respective owners.*

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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.

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

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## PROSPECTUS SUMMARY

*The following summary highlights information contained in this prospectus or incorporated by reference. While we have included what we believe to be the most important information about EOS and this offering, the following summary may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the risks of investing discussed under "Risk Factors" beginning on page 6, and the information to which we refer you and the information incorporated into this prospectus by reference, for a complete understanding of our business and this offering.*

### **Our Company**

We are a medical device company focused on the design, development and commercialization of a non-invasive, point-of-care instrument to assist in the early diagnosis of melanoma. Our flagship product MelaFind® features a hand-held imaging device that emits light of multiple wavelengths to capture images of suspicious pigmented skin lesions and extract data. The data are then analyzed utilizing image processing classification algorithms, 'trained' on our proprietary database of melanomas and benign lesions, to provide information to assist in the management of the patient, including information useful in the decision of whether to biopsy the lesion.

The components of the MelaFind® system include:

- a hand-held imaging device, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- our proprietary database of pigmented skin lesions, which we believe to be the largest in the U.S.; and
- our lesion classifiers, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions

We have entered into a binding Protocol Agreement with the U.S. Food and Drug Administration ("FDA"), which is an agreement for the conduct of the pivotal trial in order to establish the safety and effectiveness of MelaFind®. We believe the presence of the Protocol Agreement significantly enhances our ability to expedite the FDA approval process. On October 12, 2006, we announced that the FDA had informed us that when submitted the MelaFind® premarket approval, or PMA, application, would receive an expedited review. Expedited review means that upon filing our PMA, the FDA will conduct a team review, prioritize the application, and allocate sufficient resources toward a 180 day review period. While the expedited review could shorten the MelaFind® FDA approval process, we can give no assurances that this will be the case. The data accrual phase of the MelaFind® pivotal trial was completed in the third quarter of 2008 and the image processing classification algorithms were finalized in the fourth quarter. At year end 2008, the databases were undergoing third-party statistical validation and the classification algorithms were undergoing software verification and validation.

On February 13, 2009, the Company announced that a third party, independent bio-statistician had provided positive top line results from the MelaFind® pivotal clinical trial. This blinded study was conducted at seven clinical sites and included 1,831 pigmented skin lesions from 1,383 patients. We are working to complete our PMA application, which includes the final study reports, and expect to file it with the FDA during the second quarter of 2009. Upon obtaining approval from the FDA, we plan to launch MelaFind® commercially in the United States. To date, we have not generated any revenues from MelaFind®.

### **Corporate Information**

We originally incorporated in the State of New York in 1989 and subsequently reincorporated under the laws of the State of Delaware in 1997. Our executive offices are located at 3 West Main Street, Suite 201, Irvington, New York 10533. Our telephone number is (914) 591-3783.

Our website is [www.eosciences.com](http://www.eosciences.com). We make available on our website free of charge a link to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports as soon as practicable after we electronically file such material with the

Securities and Exchange Commission, or SEC. The information contained on our website or connected to our website is not incorporated by reference into and should not be considered part of this prospectus.

### **Committed Equity Financing Facility with Kingsbridge**

On May 7, 2009, we entered into a committed equity financing facility, or CEFF, with Kingsbridge, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of \$45 million or 3,327,000 shares of our common stock. In connection with the CEFF, we entered into a common stock purchase agreement and registration rights agreement with Kingsbridge, both dated May 7, 2009, and on that date we also issued a warrant to Kingsbridge to purchase up to 200,000 shares of our common stock at an exercise price of \$11.35 per share, representing a 50% premium to the average closing price of our common stock for the five days preceding the signing of the CEFF agreement. This warrant is exercisable beginning on November 7, 2009 and for a period of five years thereafter.

The shares of common stock that may be issued to Kingsbridge under the common stock purchase agreement and the warrant will be issued pursuant to an exemption from registration under the Securities Act of 1933, as amended, or the Securities Act. Pursuant to the registration rights agreement, we have filed a registration statement of which this prospectus is a part, covering the possible resale by Kingsbridge of any shares that we may issue to Kingsbridge under the common stock purchase agreement or upon exercise of the warrant.

The common stock purchase agreement entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years from the first trading day following the effectiveness of the registration statement of which this prospectus is a part, shares of our common stock for cash consideration up to an aggregate of the lesser of \$45 million or 3,327,000 shares of our common stock, subject to certain conditions and restrictions. We are not obligated to sell any shares of our common stock to Kingsbridge under the common stock purchase agreement.

For a period of 36 months from the first trading day following the effectiveness of the registration statement of which this prospectus is a part, we may, from time to time, at our sole discretion, and subject to certain conditions that we must satisfy, “draw down” funds under the CEFF by selling shares of our common stock to Kingsbridge. The purchase price of these shares will be at a discount ranging from six to ten percent of the volume weighted average of the price of our common stock for each of the eight consecutive trading days following our election to sell shares or “draw down” under the CEFF. The discount on each of these consecutive eight trading days will be determined as follows:

<u>VWAP*</u>	<u>Percent of VWAP</u>	<u>(Applicable Discount)</u>
Greater than \$10.00 per share	94%	(6)%
Less than or equal to \$10.00 per share but greater than or equal to \$6.75 per share	92%	(8)%
Less than \$6.75 per share but greater than or equal to \$2.00 per share	90%	(10)%

\* As set forth in the common stock purchase agreement, “VWAP” means the volume weighted average price (the aggregate sales price of all trades of our common stock during each trading day divided by the total number of shares of common stock traded during that trading day) of our common stock during any trading day as reported by Bloomberg L.P. using the AQR function. The VWAP and corresponding discount will be determined for each of the eight trading days during a draw down pricing period.

During the eight trading day pricing period for a draw down, if the VWAP for any trading day is less than the greater of (i) \$2.00; (ii) 90% of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down pricing period; or (iii) the price specified in the applicable draw down notice, the VWAP for that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth (1/8) of the draw down amount we had initially specified. In addition, if trading in

our common stock is suspended for any reason for more than three consecutive or non-consecutive hours during trading hours on any trading day during a draw down pricing period, that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth (1/8) of the draw down amount we had initially specified.

The maximum number of shares of common stock that we can issue pursuant to the CEFF is 3,327,000 shares. An additional 200,000 shares of common stock are issuable if Kingsbridge exercises the warrant that we issued to it in connection with the CEFF. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of stock under the CEFF provide an appropriate means of raising capital.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. We have two options under which to make individual draw downs, the fixed purchase amount option and the purchase amount option. The maximum amount of an individual draw down under the fixed purchase amount option is the lesser of \$10 million or 2.5% of our market capitalization as of the date of delivery of the applicable draw down notice. The maximum amount of an individual draw down under the purchase amount option is the lesser of \$10 million or 3.5% of our market capitalization as of the date of delivery of the applicable draw down notice or the product of the average trading volume of our common stock (as calculated in accordance with the formula set forth in the common stock purchase agreement) multiplied by the closing price of our common stock on the trading day preceding the delivery of the applicable draw down notice multiplied by 8 (the number of trading days during a draw down pricing period) multiplied by 0.25. Unless we and Kingsbridge agree otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next succeeding draw down pricing period. We are not obligated to sell shares of our common stock to Kingsbridge when the volume weighted average of the price of our common stock is below \$2.00 per share.

Furthermore, we have the right, up until October 1, 2009, to effect one draw down with a maximum amount equal to the lesser of \$4 million or 3.5% of our market capitalization as of the date of delivery of the draw down notice and a draw down discount price equal to 90% of the VWAP on each trading day during the associated draw down pricing period, which will be used in calculating the number of shares to be issued in connection with such draw down, subject to certain limitations set forth in the common stock purchase agreement.

During the term of the CEFF, without Kingsbridge's prior written consent, we may not issue securities that are, or may become, convertible or exchangeable into shares of our common stock where the purchase, conversion or exchange price for our common stock is determined using any floating discount or other post-issuance adjustable discount to the market price of our common stock, including pursuant to an equity line or other financing that is substantially similar to the arrangement provided for in the CEFF, with certain exceptions.

The issuance of our common stock under the CEFF or upon exercise of the Kingsbridge warrant will have no effect on the rights or privileges of existing holders of common stock except that the economic and voting interests of each stockholder will be diluted as a result of any issuance. Although the number of shares of common stock that stockholders presently own will not decrease, these shares will represent a smaller percentage of our total shares that will be outstanding after any issuances of shares of common stock to Kingsbridge. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if we were to issue shares when our stock price is higher. Such issuances will have a dilutive effect and may further decrease our stock price.

Kingsbridge agreed in the common stock purchase agreement that during the term of the CEFF, neither Kingsbridge nor any of its affiliates, nor any entity managed or controlled by it, will enter into, execute, or cause or assist any other person to enter into or execute, any short sale of any of our securities, including our common stock, or engage, through related parties or otherwise, in derivative transactions directly related to shares of our common stock, except during the term of a draw down pricing period with respect to the shares that Kingsbridge purchased pursuant to the CEFF during that draw down pricing period. Subject to the

foregoing restrictions, Kingsbridge has the right during any draw down pricing period to sell shares of our common stock equal in number to the aggregate number of shares of common stock purchased pursuant to the applicable draw down.

Before Kingsbridge is obligated to buy any shares of our common stock pursuant to a draw down, certain conditions must be met as of the date we notify Kingsbridge of our election to sell shares pursuant to the CEFF, each trading day during the draw down pricing period and the date upon which each settlement of the purchase and sale of our common stock occurs with respect to such draw down, including:

- Each of our representations and warranties in the common stock purchase agreement must be true and correct in all material respects as of the date when made as though made at that time, except for representations and warranties that are expressly made as of a particular date.
- We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required by the common stock purchase agreement, the registration rights agreement and the warrant to be performed, satisfied or complied with by us.
- The registration statement, of which this prospectus is a part, must have previously become effective and must remain effective and neither us nor Kingsbridge shall have received notice that the SEC has issued or intends to issue a stop order with respect to the registration statement or that the SEC, either temporarily or permanently, intends or has threatened to do so and no other suspension of the use or withdrawal of the effectiveness of the registration statement or this prospectus shall exist.
- Trading in our common stock must not have been suspended by the SEC, the NASDAQ Capital Market or the Financial Industry Regulatory Authority and trading in securities generally on the NASDAQ Capital Market must not have been suspended or limited.
- We must have sufficient shares of common stock, calculated using the closing sale price of our common stock as of the trading day immediately preceding the date we notify Kingsbridge of our election to sell shares to Kingsbridge pursuant to the CEFF, registered under the registration statement of which this prospectus is a part to issue and sell such shares in accordance with such draw down.
- We must not be in default in any material respect under the warrant.

There is no guarantee that we will be able to meet the conditions precedent or that we will be able to draw down any portion of the amounts available under the CEFF.

We also entered into a registration rights agreement with Kingsbridge, dated May 7, 2009. Pursuant to the registration rights agreement, we have filed the registration statement, of which this prospectus is a part, with the SEC relating to the resale by Kingsbridge of any shares of common stock purchased by it under the common stock purchase agreement or issued to it upon the exercise of its warrant. The effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Kingsbridge under the common stock purchase agreement. We are entitled in certain circumstances, including the existence of certain kinds of material nonpublic information, to deliver a “blackout” notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus for a period of not more than 30 days. If we deliver a blackout notice in the 20 trading days following the settlement of a draw down or if the registration statement, of which this prospectus is a part, is not effective in circumstances not permitted by the registration rights agreement, then we must pay amounts to Kingsbridge or issue Kingsbridge additional shares in lieu of payment. The payment or issuance would be calculated by means of a varying percentage of an amount based on the number of shares held by Kingsbridge that were purchased pursuant to such draw down and the change in the market price of our common stock between the date the blackout notice is delivered (or the registration statement is not effective) and the date the prospectus again becomes available.

We may terminate the CEFF upon one trading day’s notice to Kingsbridge, except that we may not terminate the CEFF during any draw down pricing period. Kingsbridge may, upon one trading day’s notice to us, terminate the CEFF if we enter into a transaction prohibited by the common stock purchase agreement without Kingsbridge’s prior written consent or if Kingsbridge provides notice to us of a material adverse event relating to our business and the event continues for 10 trading days after the notice. Kingsbridge may also

terminate the CEFF upon one trading day's notice to us at any time in the event that a registration statement is not initially declared effective in accordance with the registration rights agreement. In addition, either we or Kingsbridge may terminate the CEFF upon one trading day's notice if the other party has breached a material representation, warranty or covenant to the common stock purchase agreement and such breach is not remedied within 10 trading days after notice of such breach is delivered to the breaching party. In the event of a termination of the CEFF by Kingsbridge or us pursuant to the terms of the CEFF, Kingsbridge would retain the warrant to purchase 200,000 shares of our common stock.

In connection with the CEFF, we will pay up to \$75,000 to Kingsbridge to cover the costs of their legal fees and expenses. In addition, we must pay Kingsbridge \$12,500 per quarter for each quarter we do not make a drawdown under the CEFF of at least 2% of the our market capitalization.

The foregoing summary of the CEFF does not purport to be complete and is qualified by reference to the common stock purchase agreement, the registration rights agreement and the warrant, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.



## RISK FACTORS

*This offering involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information contained in this prospectus, or incorporated into this prospectus by reference, including the section entitled "Special Note Regarding Forward-Looking Statements," before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition or operating results could be harmed. In that case, the trading price of our common stock could decline, and you may lose part or all of your investment. The risks and uncertainties described below are not the only ones facing EOS. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations and adversely affect the market price of our common stock.*

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

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

We currently do not have any commercialized products or any significant source of revenue. We have invested substantially all of our time and resources over the last seven years in developing MelaFind®. MelaFind® may require additional development and clinical evaluation and it will require regulatory approval, significant marketing efforts and substantial additional investment before it can provide us with any revenue. On February 13, 2009, we announced the top-line results of our pivotal clinical trial relating to MelaFind®. While we believe that the top-line results support submission of the PMA, commercialization of MelaFind® remains subject to certain risks. Our efforts may not lead to commercially successful products for a number of reasons, including:

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

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

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

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

- MelaFind® may not be safe or effective to the FDA's satisfaction;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;

- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

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

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

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

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

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

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

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

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

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

***The FDA may require additional clinical trials and any adverse results in such clinical trials, or difficulties in conducting such clinical trials, could have a material adverse effect on our business.***

While the Company has completed its pivotal clinical trials on which it intends to base the MelaFind® PMA, upon evaluation of the MelaFind® PMA, the FDA may require us to conduct additional clinical studies. The occurrence of unexpected findings in connection with any subsequent clinical trial required by the FDA may prevent or delay obtaining PMA approval. In addition, subsequent clinical studies would require the expenditure of additional Company resources and could be a long and expensive process subject to unexpected delays. Any adverse results in such clinical trials, or difficulties in conducting such clinical trials, could have a material adverse effect on our business.

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

We began operations in December 1989. At that time, we provided research services, mostly to U.S. government agencies, on classified projects. We have financed our operations since 1999 primarily through the sale of our equity securities and have devoted substantially all of our resources to research and development relating to MelaFind®. Our net loss for the three months ended March 31, 2009 was

approximately \$4.0 million and as of March 31, 2009, we had an accumulated deficit of approximately \$64.8 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind®. If we receive PMA approval for MelaFind® from the FDA, we expect to incur significant sales and marketing expenses, which will require additional funding, and manufacturing expenses. Additionally, our general and administrative expenses have also increased due to the additional operational and regulatory responsibilities applicable to public companies. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

We do not know of any product possessing the diagnostic assistance capabilities of MelaFind®. We believe that electro-optical products designed to enhance the visualization and analysis of potential melanomas have been approved or are under development by: Welch Allyn, Inc., Heine Optotechnik, 3Gen, LLC, Derma Medical Systems, Inc., Medical High Technologies S.p.A., ZN Vision Technologies AG, Polartechnics, Ltd., Astron Clinica, Ltd., Biomips Engineering, and SciBase AB. The broader market for precision optical imaging devices used for medical diagnosis is intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. If our products are approved for marketing, we will potentially be subject to competition from major optical imaging companies, such as: Raytheon Corporation, General Electric Co., Siemens AG, Bayer AG, Eastman Kodak Company, Welch Allyn, Inc., Olympus Corporation, Carl Zeiss AG Deutschland, and others, each of which manufactures and markets precision optical imaging products for the medical market, and could decide to develop or acquire a product to compete with MelaFind®. These companies enjoy numerous competitive advantages, including:

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

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

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

The precision optical imaging field is subject to rapid technological change and product innovation. MelaFind® is based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies. Companies in the medical device industry with significantly greater financial, technical, research, marketing, sales and distribution and other resources have expertise and interest in the exploitation of computer-aided diagnosis, medical imaging, and other technologies MelaFind® utilizes. Some of these companies are working on potentially competing products or therapies, including confocal microscopy (a type of scanning microscopy for 3-dimensional specimens, which produces blur-free images at various depths), various forms of spectroscopy (a study of the way molecules absorb and emit light), other imaging modalities, including molecular imaging in which tagged antibodies search for cancer cell antigens, and molecular and genetic screening tests. Molecular-based approaches are being investigated; Dermtech is exploring Messenger RNA analysis of surface cells, for example. Several additional approaches to detecting

Melanoma have been identified. Balter Medical (Norway) uses ‘Optical Transfer Diagnosis’ to identify Melanomas. The technology measures how much light is absorbed in healthy versus diseased tissue to determine whether cancer is present. Raytheon Corporation, partnered with Arizona Cancer Center, utilizes satellite-based remote imaging technology in detecting skin changes that could indicate the presence of cancer. Vanderbilt University has introduced technology called ‘Confocal Raman Micro-Spectroscopy’. The technology uses a reflective laser to produce a molecular fingerprint of the underlying tissue to indicate the presence or absence of disease. In addition, the National Institutes of Health and other supporters of cancer research are presumptively seeking ways to improve the diagnosis or treatment of melanoma by sponsoring corporate and academic research. There can be no assurance that one or more of these companies will not succeed in developing or marketing technologies and products or services that demonstrate better safety or effectiveness, superior clinical results, greater ease of use or lower cost than MelaFind®, or that such competitors will not succeed in obtaining regulatory approval for introducing or commercializing any such products or services prior to us. FDA approval of a commercially viable alternative to MelaFind® produced by a competitor could significantly reduce market acceptance of MelaFind®. Any of the above competitive developments could have a material adverse effect on our business, financial condition, and results of operations. There is no assurance that products, services, or technologies introduced prior to or subsequent to the commercialization of MelaFind® will not render MelaFind® less marketable or obsolete.

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

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

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

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

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

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

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

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

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

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

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

- potential advantages over alternative diagnostic methodologies;
- introduction and acceptance of competing products or technologies; and
- extent and success of our sales, marketing and distribution efforts.

The success of MelaFind® will depend upon the acceptance by dermatologists and other physicians who perform skin examinations and treat skin disorders, including industry opinion leaders, that the diagnostic information provided by MelaFind® is medically useful and reliable. We will be subject to intense scrutiny before physicians will be comfortable incorporating MelaFind® in their diagnostic approaches. We believe that recommendations by respected physicians will be essential for the development and successful marketing of MelaFind®; however, there can be no assurance that any such recommendations will be obtained. To date, the medical community outside the limited circle of certain dermatologists specializing in melanoma has had little exposure to us and MelaFind®. Because the medical community is often skeptical of new companies and new technologies, we may be unable to gain access to potential customers in order to demonstrate the operation and effectiveness of MelaFind®. Even if we gain access to potential customers, no assurance can be given that members of the dermatological, or later the general practice, medical community will perceive a need for or accept MelaFind®. In particular, given the potentially fatal consequences of failing to detect melanoma at the early, curable stages, practitioners may remain reluctant to rely upon MelaFind® even after we receive approval from the FDA for marketing the product. Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind®. Insufficient market acceptance of MelaFind® would have a material adverse effect on our business, financial condition and results of operations.

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

As of March 31, 2009, we had \$11.2 million in cash and cash equivalents and \$0.4 million in marketable securities. Our operations have consumed substantial amounts of cash for each of the last eight years. We may require funds in addition to our CEFF with Kingsbridge to pursue regulatory approvals and to achieve significant commercialization of MelaFind®. However, there can be no assurances that we will be able to raise additional capital in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term.

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

- suppliers may make errors in manufacturing components that could negatively impact the effectiveness or safety of our products, or cause delays in shipment of our products;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

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

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

We have entered into a development agreement with ASKION to complete developmental engineering and testing of our hand-held imaging device, and have also entered into a production agreement with ASKION to assemble the components and produce initial quantities of our hand-held imaging devices. We intend to enter into a contract for commercial production of the hand-held imaging devices once commercial specifications for MelaFind® have been finalized, but we may not be able to enter such an agreement on mutually acceptable terms. Failure to enter into such an agreement with ASKION would require us to expand our own manufacturing facilities or obtain such services elsewhere. Similarly, we have entered into a confidentiality agreement and a development agreement with Zeiss for lenses and lens objective assemblies, and we have entered into a contract for the commercial production of lenses. The manufacturing agreement with ASKION will include integration of the Zeiss lenses in the hand-held imaging devices. Our planned reliance upon an outside provider for assembly and production services subjects us to the risk of adverse consequences from delays and defects caused by the failure of such outside supplier to meet its contractual obligations, including confidentiality obligations in the case of Zeiss, which is an affiliate of Carl Zeiss AG, a potential competitor. The failure by us or our supplier to produce a sufficient number of hand-held imaging devices that can operate according to our specifications could delay the commercial sale of MelaFind®, and would adversely affect both our ability to successfully commercialize MelaFind® and our business, financial condition and results of operations.

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

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

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continuous review and

periodic inspections by the FDA and other regulatory bodies. In particular, we and our suppliers are required to comply with the QSR and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, promotion, distribution, and shipping of MelaFind®, and with record keeping practices. We also will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports and registration and listing requirements. To the extent that we contract with third parties to manufacture some of our products, our manufacturers will be required to adhere to 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 inspected or must have been inspected, and must be in full compliance with cGMP requirements before approval for marketing. The FDA enforces the QSR and other regulatory requirements through unannounced inspections. We have not yet been inspected by the FDA for MelaFind® and will have to complete such an inspection successfully before we ship any commercial MelaFind® devices.

Our full-time director of quality assurance and regulatory affairs continues to address the inspectional findings, particularly as they relate to current MelaFind® design development and ultimately MelaFind® commercial manufacturing. If we are not successful in convincing the FDA that we are capable of addressing any concerns it might have relative to MelaFind®, or in our efforts to address any MelaFind® deficiencies that might develop, we could be subject to additional FDA action of a type described below, which could negatively affect our ability to commercialize MelaFind®. There can be no assurance that the future interpretations of legal requirements made by the FDA or other regulatory bodies with possible retroactive effect, or the adoption of new requirements or policies, will not adversely affect us. We may be slow to adapt, or may not be able to adapt, to these changes or new requirements. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions:

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

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

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

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

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

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

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

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

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

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and the Civil Monetary Penalties Law, which authorizes HHS to impose civil penalties administratively for fraudulent or abusive acts. Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out

waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use of MelaFind® by physicians may dissuade physicians from either purchasing or using MelaFind® and could have a material adverse effect on our ability to commercialize MelaFind®.

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

HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates “covered entities” (insurers, clearinghouses, and most healthcare providers) and indirectly regulates “business associates” with respect to the privacy of patients’ medical information. Certain entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information.

It is uncertain whether we would be deemed to be a covered entity under HIPAA, and it is unlikely that based on our current business model, we would be a business associate. Nevertheless, we will likely be contractually required to physically safeguard the integrity and security of the patient information that we or our physician customers receive, store, create or transmit. If we fail to adhere to our contractual commitments, then our physician customers may be subject to civil monetary penalties, and this could adversely affect our ability to market MelaFind®. We also may be liable under state laws governing the privacy of health information.

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

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

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

We also may rely on our patents, patent applications and other intellectual property rights to give us a competitive advantage. Whether a patent is valid, or whether a patent application should be granted, is a

complex matter of science and law, and therefore we cannot be certain that, if challenged, our patents, patent applications and/or other intellectual property rights would be upheld. If one or more of those patents, patent applications and other intellectual property rights are invalidated, rejected or found unenforceable, that could reduce or eliminate any competitive advantage we might otherwise have had.

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

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

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

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

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

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

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

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

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

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

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

If there is a connection between the MelaFind® hand-held imaging device and the central server in our offices, it will be dependent on the internet. We may use the internet as a medium to provide quality control calibration services to physicians. We also plan to use the internet to inform the public about the availability of our products and to market to and communicate with physicians who are potential or actual customers. Our success will therefore depend in part on the continued growth and use of the internet. If our ability to use the internet fails, it may materially adversely affect our business.

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

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

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

All of our operations are conducted at two adjacent buildings in Irvington, New York. We take precautions to safeguard our facility, including insurance, health and safety protocols, contracted off-site engineering services, and storage of computer data. However, a natural disaster, such as a fire, flood or

earthquake, could cause substantial delays in our operations, damage or cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

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

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

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

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

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

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

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

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



to divert immediate and substantial attention to seeking a replacement. Each of our officers may terminate their employment at any time without notice and without cause or good reason.

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

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

We have granted to certain employees stock options that vest with the attainment of various performance milestones. Upon the attainment of these milestones we will be required to recognize a stock based compensation expense in an amount based on the fair value of the options. We have also granted options that vest upon attainment of development milestones. Upon the attainment of each of the relevant development milestones which include submission of the PMA application for MelaFind® and FDA approval of such PMA, there will be a significant compensation charge based on the then fair value of such options.

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

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

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

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

## Risks Relating to Our Common Stock

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

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

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

Our stock price is likely to be volatile. Between October 28, 2005 (the date of our initial public offering) and March 31, 2009, our stock price has ranged from \$2.29 to \$9.99 per share. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:

- results of our research and development efforts and our clinical trials;
- the timing of regulatory approval for our products;
- failure of any of our products, if approved, to achieve commercial success;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the US and foreign countries;
- ability to manufacture our products to commercial standards;
- developments concerning our clinical collaborators, suppliers or marketing partners;
- changes in financial estimates or recommendations by securities analysts;
- public concern over our products;
- developments or disputes concerning patents or other intellectual property rights;
- product liability claims and litigation against us or our competitors;
- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of and third-party reimbursement in the 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 stockholders to lose some or all of their investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly. Whether or not meritorious, litigation brought against us could result in substantial costs and could divert the time and attention of our management. Our insurance to cover claims of this sort may not be adequate.

***If our directors, executive officers, and principal stockholders choose to act together, they may have the ability to influence all matters submitted to stockholders for approval.***

As of March 31, 2009, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates in the aggregate, beneficially owned approximately 16% of our outstanding common stock. As a result, these stockholders, subject to any fiduciary duties owed to our other stockholders under Delaware law, could be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your interests. The concentration of ownership could delay or prevent a change in control of our company or otherwise discourage a potential acquirer from attempting to obtain control of our company, which in turn could reduce the price of our common stock. In addition, these stockholders, some of whom have representatives sitting on our Board of Directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes of control of our company, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

***Our charter documents 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 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.

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.

**Risks Relating to the Committed Equity Financing Facility with Kingsbridge**

***We will not be able to make a draw under the Committed Equity Financing Facility that we entered into with Kingsbridge unless certain conditions are met.***

The Committed Equity Financing Facility, or CEFF, with Kingsbridge entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock of \$2.00 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of the registration statement of which this prospectus is a part; and the continued listing of our stock on the NASDAQ Capital Market. Therefore, if we are unable to satisfy these pre-conditions, we will not be able to require Kingsbridge to buy any shares of common stock and will not be able to raise any funds under the CEFF.

***The Committed Equity Financing Facility that we entered into with Kingsbridge will not be available to us if Kingsbridge terminates the CEFF in accordance with its terms.***

Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides us notice of such material and adverse event. If the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

***The CEFF that we entered into with Kingsbridge may require us to make additional “blackout” or other payments to Kingsbridge.***

In connection with our CEFF with Kingsbridge, we are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement of which this prospectus is a part and prohibit Kingsbridge from selling shares under this prospectus. If we deliver a blackout notice in the 20 trading days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the agreement, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of the number of shares held by Kingsbridge (exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant) and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout or other payment could be significant.

***The CEFF that we entered into with Kingsbridge may result in dilution to our stockholders if we sell shares to Kingsbridge under the CEFF or issue shares in lieu of a blackout payment.***

Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effective on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10 percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if we were to issue shares when our stock price is higher. Such issuances will have a dilutive effect and may further decrease our stock price.

#### **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 shares of our common stock by the selling stockholder pursuant to this prospectus. Any issuance of shares by us to Kingsbridge under the common stock purchase agreement or in connection with the exercise of the Kingsbridge warrant will be made pursuant to an exemption from the registration requirements of the Securities Act. To the extent we are able to sell shares under the CEFF to Kingsbridge, we may receive a maximum of \$45 million. To the extent the warrant held by the selling stockholder is exercised in full at its current exercise price, we would receive \$2,270,000 in cash proceeds, unless such warrant is exercised on a cashless basis pursuant to its terms.

Unless otherwise provided in the applicable prospectus supplement, we intend to use the proceeds from our sales, if any, to Kingsbridge to finance the PMA application process, the commercialization of MelaFind® and for general corporate purposes, including capital expenditures and working capital. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress in and costs of our PMA application for MelaFind®, and the amount of cash used by our operations. We therefore cannot estimate the amount of proceeds to be used for all of the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the proceeds. Pending the uses described above, we intend to invest the proceeds temporarily in short-term or marketable securities until we use them for their stated purpose.

### SELLING STOCKHOLDER

This prospectus relates to the possible resale by the selling stockholder, Kingsbridge, of shares of common stock that we may issue pursuant to the common stock purchase agreement we entered into with Kingsbridge on May 7, 2009, or upon exercise of the warrant that we issued to Kingsbridge on May 7, 2009. We are filing the registration statement, of which this prospectus is a part, pursuant to the provisions of the registration rights agreement we entered into with Kingsbridge on May 7, 2009. The selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares that it acquires under the common stock purchase agreement or upon exercise of the warrant.

The following table presents information regarding Kingsbridge, as the selling stockholder, and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of May 7, 2009. As used in this prospectus, the term “selling stockholder” includes Kingsbridge and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from the 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 stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the 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. The percentage of shares of common stock beneficially owned prior to the offering shown in the table below is based both on an aggregate of 17,639,498 shares of our common stock outstanding on May 7, 2009.

<u>Selling Stockholder</u>	<u>Shares Beneficially Owned Prior to the Offering</u>	<u>Number of Shares Being Offered</u>	<u>Shares Beneficially Owned After the Offering</u>
Kingsbridge Capital Limited(1)	3,527,000(2)	3,527,000(2)	0

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- (1) The business address of Kingsbridge Capital Limited is P.O. Box 1075, Elizabeth House, 9 Castle Street, St. Helier, Jersey, JE42QP, Channel Islands. Adam Gurney, Tony Gardner-Hillman and Maria O'Donoghue have shared voting and investment control of the securities held by Kingsbridge.
  - (2) Consists of 3,327,000 shares of common stock, the maximum number of shares of common stock issuable under the common stock purchase agreement we entered into with Kingsbridge on May 7, 2009, and 200,000 shares of common stock issuable upon exercise of a warrant issued to Kingsbridge on May 7, 2009. For the purposes hereof, we assume the issuance of all 3,527,000 shares.

#### **PLAN OF DISTRIBUTION**

To the extent that we issue shares to Kingsbridge under the CEFF or Kingsbridge acquires shares upon exercise of its warrant, the selling stockholder may offer such shares for resale under this prospectus. Except as described below, to our knowledge, the selling stockholder has not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares of common stock offered hereby, nor, except as described below, do we know the identity of the brokers or market makers that will participate in the resale of the shares.

The selling stockholder may decide not to sell any shares. The selling stockholder may from time to time offer some or all of the shares of common stock through brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholder may arrange for other broker-dealers to participate. Kingsbridge is an "underwriter" within the meaning of the Securities Act. Any brokers, dealers or agents who participate in the distribution of the shares of common stock by the selling stockholder may also be deemed to be "underwriters," and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts and commissions under the Securities Act. To the extent the selling stockholder may be deemed to be an underwriter, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934.

The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale by it. Such sales may be made on the NASDAQ Capital Market, on the over-the-counter market, otherwise, or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold by the selling stockholder according to one or more of the following methods:

- a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus;
- an over-the-counter distribution in accordance with the rules of the NASDAQ Stock Market;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- privately negotiated transactions;
- a combination of such methods of sale; and
- any other method permitted pursuant to applicable law.

Any shares covered by this prospectus which qualify for sale pursuant to Rule 144 of the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. In addition, the selling stockholder may transfer the shares by other means not described in this prospectus.

Any broker-dealer participating in such transactions as agent may receive commissions from Kingsbridge (and, if they act as agent for the purchaser of such shares, from such purchaser). Broker-dealers may agree with Kingsbridge to sell a specified number of shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for Kingsbridge, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to Kingsbridge. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) on the NASDAQ Capital Market, on the over-the-counter market, in privately-negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above. To the extent required under the Securities Act, an amendment to this prospectus or a supplemental prospectus will be filed, disclosing:

- the name of any such broker-dealers;
- the number of shares involved;
- the price at which such shares are to be sold;
- the commission paid or discounts or concessions allowed to such broker-dealers, where applicable;
- that such broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and
- other facts material to the transaction.

Underwriters and purchasers that are deemed underwriters under the Securities Act may engage in transactions that stabilize, maintain or otherwise affect the price of the securities, including the entry of stabilizing bids or syndicate covering transactions or the imposition of penalty bids. Kingsbridge and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases by the selling stockholder or other persons or entities. Under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to special exceptions or exemptions. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. The anti-manipulation rules under the Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

We have agreed to pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees, as well as certain fees of counsel for the selling stockholder incurred in the preparation and negotiation of the CEFF agreements and the registration statement of which this prospectus forms a part. The selling stockholder will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as transfer taxes and certain other expenses associated with its sale of securities.

Under the terms of the Kingsbridge common stock purchase agreement and the registration rights agreement, we have agreed to indemnify the selling stockholder and certain other persons against certain liabilities in connection with the offering of the shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute toward amounts required to be paid in respect of such liabilities.

At any time a particular offer of the shares of common stock is made by the selling stockholder, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC, to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock. We may suspend the sale of shares by the

selling stockholder pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

#### **LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon by Golenbock Eiseman Assor Bell & Peskoe LLP, New York, New York.

#### **EXPERTS**

The financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2008 have been audited by Eisner LLP, an independent registered public accounting firm as stated in their reports incorporated herein by reference, which reports have been so incorporated in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

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

We are a public company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. Our SEC filings are also available to the public at the SEC's website at <http://www.sec.gov>.

In addition, we maintain a website that contains information regarding our company, including copies of reports, proxy statements and other information we file with the SEC. The address of our website is [www.eosciences.com](http://www.eosciences.com). Our website, and the information contained on that site, or connected to that site, are not intended to be part of this prospectus.

We have filed a registration statement on Form S-3 with the SEC for the common stock offered by the selling stockholder under this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information that is not contained in this prospectus. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document. You may:

- inspect a copy of this prospectus, including the exhibits and schedules, without charge at the public reference room;
- obtain a copy from the SEC upon payment of the fees prescribed by the SEC; or
- obtain a copy from the SEC website.

#### **INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC allows us to "incorporate by reference" into this prospectus the information contained in the documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will update and supersede this information. We are incorporating by reference the following documents into this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2008 (including information specifically incorporated by reference into our Form 10-K from our Proxy Statement for our 2009 Annual Meeting of Stockholders);



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- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009;
- our Current Reports on Form 8-K filed on February 13, 2009 and May 8, 2009; and
- the description of our common stock contained in our registration statement on Form 8-A and any amendments or reports filed for the purpose of updating such description.

We are also incorporating by reference any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus and prior to the termination of the offering of the securities to which this prospectus relates. In no event, however, will any of the information that we “furnish” to the SEC or is not deemed “filed” with the SEC in any Current Report on Form 8-K or any other report or filing be incorporated by reference into, or otherwise included in, this prospectus.

You may access our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statement, and amendments, if any, to those documents filed or furnished pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act with the SEC free of charge at the SEC’s website or our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

You may request of copy of these filings, at no cost, by writing to Richard I. Steinhart, Chief Financial Officer, Electro-Optical Sciences, Inc., 3 West Main Street, Suite 201, Irvington, New York 10533 or by telephone at (914) 591-3783.