Filed Pursuant to Rule 424(b)(4)
Registration No. 333-125517

PROSPECTUS

4,000,000 Shares
Common Stock
$5.00 per Share

This is the initial public offering of shares of common stock by Electro-Optical Sciences, Inc.

We are offering 4,000,000 shares of our common stock. The initial public offering price is $5.00 per share. Prior to this offering, there has been no public market for our common stock and we cannot ensure you that a market will develop.

We have applied to have our common stock included for quotation on the NASDAQ Capital Market under the symbol “MELA.”

Investing in our common stock is highly speculative and involves a high degree of risk. See “Risk factors” beginning on Page 7 to read about factors you should consider before buying shares of our common stock.

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.

	Per Share	Total
Public offering price	$ 5.00	$ 20,000,000
Underwriting discounts and commissions	$ .35	$ 1,400,000
Proceeds, before expenses, to Electro-Optical Sciences, Inc.	$ 4.65	$ 18,600,000

We granted the underwriters the right to purchase up to an additional 600,000 shares of common stock from us at the public offering price less the underwriting discount, to cover any over-allotments. The underwriters can exercise this right at any time within 30 days from the date of this prospectus. The underwriters will also receive a non-accountable expense allowance in the amount of one percent (1%) of the total public offering price (excluding the over-allotment option). In addition, upon completion of this offering, the underwriters will receive warrants to purchase up to an aggregate of 150,000 shares of our common stock at an exercise price equal to 125% of the public offering price per share. The warrants will be exercisable commencing on the first anniversary of the date of this prospectus and ending on the fifth anniversary of the date of this prospectus.

We expect that delivery of the shares will be made to investors on or about November 2, 2005.

ThinkEquity Partners LLC **Stanford Group Company**

October 28, 2005.

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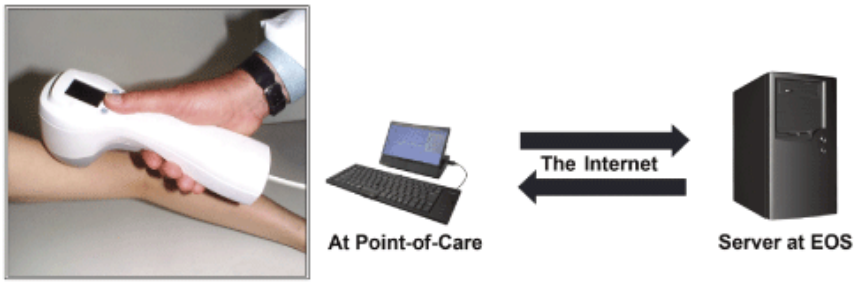
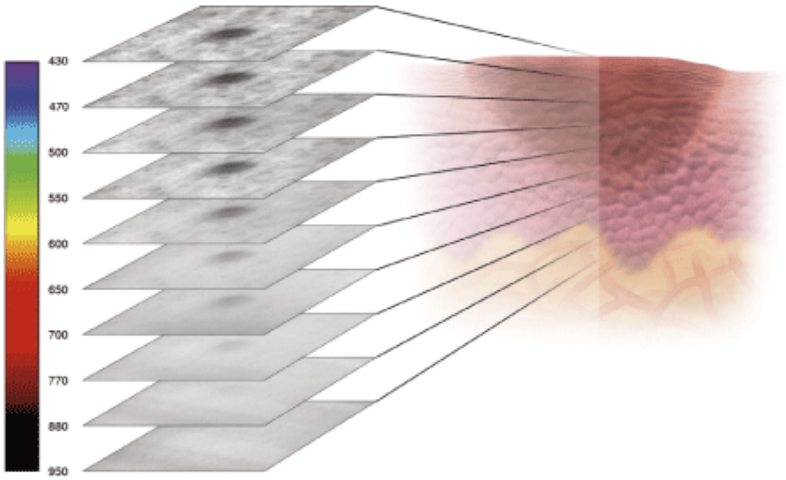
The MelaFind® System



MelaFind® is a non-invasive system for assisting in the early detection of melanoma. The MelaFind® system is comprised of a point-of-care, hand-held imaging device that, in commercial use, is intended to be connected via the internet to a central server located at EOS. When marketed, a report will be transmitted to the physician's office containing MelaFind®'s recommendation of whether the lesion should be biopsied.



Traditional visual clinical examination is limited to the surface appearance of the suspicious pigmented skin lesion, whereas MelaFind® utilizes information derived from up to 2.5mm deep into the skin. MelaFind® uses an illuminator that shines 10 different specific wavelengths of light (from 430nm to 950nm), including near infra-red bands, which penetrate to varying depths of skin. The data are analyzed against our proprietary database of melanomas and benign lesions using our sophisticated algorithms.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. We are not making an offer to sell shares of our common stock and are not seeking offers to buy shares of our common stock in jurisdictions where offers and sales are not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the common stock.

Until November 22, 2005 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the US: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the US. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

We obtained statistical data and certain other industry forecasts used throughout this prospectus from market research, publicly available information and industry publications. Industry publications generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy and completeness of the information. Similarly, while we believe that the statistical and industry data and forecasts and market research used herein are reliable, we have not independently verified such data. We have not sought the consent of the sources to refer to their reports in this prospectus.

SPECIAL SUITABILITY FOR CALIFORNIA RESIDENTS

Our common stock may only be purchased by natural persons resident in California who:

1. are natural persons whose individual net worth or whose net worth with that person's spouse, at the time of the purchase exceeds $250,000; or
2. had an individual income in excess of $65,000 in each of the two most recent years or joint income with that person's spouse in excess of $100,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year.

Any such person, in addition, may not purchase shares of our common stock having an aggregate value in excess of 10% of such person's net worth.

Summary

This summary highlights information contained elsewhere in this prospectus. It does not contain all of the information you should consider before buying shares of our common stock. You should read this entire prospectus carefully, especially the "Risk factors" section and our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in shares of our common stock. Unless otherwise stated or the context otherwise requires, reference in this prospectus to "EOS," "we," "us," "our" and similar references refer to Electro-Optical Sciences, Inc.

Business

We are a medical device company focused on the design and development 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 multiple wavelengths of light to capture images of suspicious pigmented skin lesions and extract data. The data are then analyzed against our proprietary database of melanomas and benign lesions using our sophisticated algorithms in order to provide information to the physician and produce a recommendation of whether the lesion should be biopsied.

The components of the MelaFind® system include:

- a *hand-held imaging device*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- our *proprietary database* of pigmented skin lesions, which we believe to be the largest in the US;
- our *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions; and
- a *central server* in our offices that is intended to perform quality control functions and provide reports to the physician and in commercial use, wil be connected to physicians' offices via the internet.

We have entered into a binding Protocol Agreement with the US 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. We stopped a study that was initiated in late 2004 under the Protocol Agreement due to technical difficulties with some of the MelaFind® clinical trial instruments. The FDA has provided confirmation that our plan to correct the technical issues and start a new pivotal trial to satisfy the Protocol Agreement is acceptable. Management estimates that the pivotal trial will commence in early 2006 at over 20 US clinical study sites, and anticipates premarket approval (PMA) to commercialize MelaFind® in 2007.

To date, we have not generated any revenues from MelaFind®. All of our historical revenues have come from activities and products that have since been discontinued, including our DIFOTI® product, a non-invasive imaging device for the detection of dental cavities. We decided to discontinue all operations associated with our DIFOTI® product, effective as of April 5, 2005, in order to focus our resources on the development and commercialization of MelaFind®.

The Market Opportunity

Cancer of the skin has a higher incidence than all other cancers combined, and the rates are rising dramatically. In 2005, over 120,000 new cases of melanoma are projected. Melanoma is responsible for approximately 80% of skin cancer fatalities and is the deadliest of all skin cancers as there is currently no cure for advanced stage melanoma. However, early detection of melanoma can lead to virtually a 100% cure rate. Therefore, the need for medical practitioners to be able to examine individuals during a routine annual exam, resulting in early detection and treatment of skin cancer cannot be overstated. Advanced stage melanoma is costly to treat and is responsible for approximately 90% of the total spending on melanoma treatment in the US, costing up to $170,000 per patient. If diagnosed early, however, melanoma is almost always cured by simple resection at a cost of approximately $1,800 per patient.

Melanoma is currently the subject of significant attention in the medical community. In part, this attention is due to the fact that it is the fastest growing cancer. It is also the most common cancer in young adults ages 20-30, and currently there are more new cases of melanoma than HIV/ AIDS. In women ages 25-30, melanoma is the primary cause of cancer death. In women ages 30-35, melanoma is the second leading cause of death after breast cancer. Recent published papers identify a strong correlation between breast cancer and melanoma.

Because early detection is critical to survival, the American Cancer Society recommends that individuals 40 years and older have complete skin examinations on an annual basis. According to the 2000 US Census data, over 100 million Americans in the US are over age 40. Furthermore, there are more than 20 million individuals in the US who have dysplastic nevi, a type of pigmented skin lesion that when present is associated with an increased risk of melanoma. These individuals warrant more frequent observation.

Limitations of Current Melanoma Diagnosis

Melanomas are mainly diagnosed by dermatologists and/or primary care physicians using only visual clinical evaluation. Physicians assess pigmented skin lesions using the "ABCDE" criteria, Asymmetry, Border irregularity, Color variation, Diameter greater than 6 mm, and Evolving — change in ABCD over time. This assessment is subjective and results in missed melanomas, as well as a ratio of benign lesions biopsied to melanomas confirmed that is highly variable and as high as 40 to 1 for dermatologists and as high as 50 to 1 for primary care physicians.

Dermatologists who specialize in the management of pigmented skin lesions may also use dermoscopy, a method of viewing lesions under magnification. Approximately 25% of dermatologists use dermoscopy. Although dermoscopy provides more information than unaided visual examination, mastery of the technique necessitates many years of training and experience. Proper use of dermoscopy can reduce the number of unnecessary biopsies of benign lesions, but even dermoscopy experts biopsy 3-10 benign lesions for every melanoma detected.

In contrast, MelaFind® delivers an objective assessment based on numerical scores assigned to the suspicious skin lesion under evaluation and does not require extensive physician training to operate. Further, visual clinical evaluation is limited to the surface appearance of the suspicious pigmented skin lesion, whereas MelaFind® utilizes information derived from up to 2.5 mm deep into the skin. In clinical trials to date, this objective assessment has resulted in a ratio of benign lesions biopsied to melanomas confirmed as low as almost 2 to 1.

Clinical Results to Date

To date, MelaFind® has been studied on over 5,000 skin lesions from over 3,500 patients at over 20 clinical centers. Our clinical studies have demonstrated that MelaFind® missed fewer melanomas and produced fewer false positives than were experienced by study dermatologists, who are skin cancer specialists. The performance of a diagnostic is measured in terms of "sensitivity" (the ability to detect disease when disease is present) and "specificity" (the ability to exclude disease when disease is not present). In the largest blinded trial that we have performed to date on 352 suspicious pigmented skin lesions, MelaFind® did not miss a melanoma (measured sensitivity of 100%) and achieved 48.4% specificity, compared to the study dermatologists' sensitivity of 96.4% and specificity of 28.4%.

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

Our Strategy

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

- **Pursue timely FDA approval of MelaFind®.** We have entered into a binding Protocol Agreement with the FDA for the conduct of the pivotal trial of MelaFind®. Management estimates that the study will commence in early 2006 at over 20 US clinical study sites, and anticipates PMA approval to commercialize MelaFind® in 2007.

- **Establish MelaFind® as the leading technology for assisting in the detection of melanoma.** We have invested considerable capital and expertise into developing our core technology platform, which is protected by six US patents. We will continue to refine and optimize this technology to ensure that MelaFind® is the leading system for assisting in the detection of melanoma.
- **Obtain third party payor reimbursement to support our recurring revenue pricing model.** We intend to offer MelaFind® on a per patient basis, creating a recurring revenue stream. To do so, we will seek to obtain third party reimbursement as well as private pay alternatives. We are working with experts to create an evidence-based medicine evaluation model consistent with those used to support positive coverage decisions by the federal Centers for Medicare & Medicaid Services (CMS) and private payors for similar products. The value drivers in the model include the treatment and diagnostic cost savings associated with early detection (approximately $168,000 per patient) and fewer biopsies. We believe that the use of MelaFind® could result in substantial savings to the US healthcare system.
- **Commercialize MelaFind® using multiple sales and marketing strategies.** Our sales and marketing effort will focus initially on "high volume/key opinion leader" dermatologists with specialties in the diagnosis and treatment of melanoma. To enter the larger US markets of general dermatologists, plastic surgeons, and primary care physicians, and for international markets, we intend to establish partnerships with pharmaceutical and/or diagnostic device companies with an established presence in these markets. While we believe obtaining a positive coverage decision from CMS may take an additional 18 to 36 months following PMA approval, and obtaining a positive coverage decision from private payors, managed care organizations and state Medicare administrative contractors may take at least 6 to 12 months following PMA approval, we intend to commence sales of MelaFind® immediately upon receiving PMA approval for physicians to offer MelaFind® to their patients on a self-pay basis.

Company Information

We were incorporated under the laws of 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 websites include www.eo-sciences.com and www.melafind.com. The information contained on our websites is not a part of this prospectus and should not be relied upon. We hav included our website addresses in this document as inactive textual references only.

This prospectus contains references to our US registered trademarks: MelaFind®, DIFOTI®, 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.

The offering

Common stock offered by us	4,000,000 shares
Common stock outstanding after the offering	10,513,164 shares
Use of proceeds	We estimate that our net proceeds from this offering will be approximately $16.5 million based on the initial public offering price of $5.00 per share, after deducting estimated underwriting discounts and commissions and offering expenses payable by us. We intend to use these net proceeds to fund our research and development activities, including our clinical studies, toward development of our sales and marketing capabilities, and for general corporate purposes, including working capital needs and facilities expansion. See “Use of proceeds.”
Risk factors	You should read the “Risk factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Capital Market symbol	MELA

The number of shares of our common stock to be outstanding after this offering is based on 6,513,164 shares outstanding as of August 31, 2005, and unless otherwise indicated, excludes:

- 899,875 shares of common stock issuable as of the date of this prospectus upon the exercise of outstanding stock options under our 2003 Stock Incentive Plan and our 1996 Stock Option Plan, respectively, at a weighted average exercise price of approximately $0.64 per share;
- up to 1,000,000 shares of common stock reserved for future grants under our 2005 Stock Incentive Plan;
- 75,000 shares of common stock issuable upon exercise of outstanding warrants to purchase common stock at an exercise price of $7.00 per share;
- 73,280 shares of common stock issuable upon exercise of outstanding warrants to purchase our Series C preferred stock (assuming conversion of our Series C preferred stock) at an exercise price of $4.52 per share; and
- 150,000 shares of common stock issuable upon exercise of warrants to be issued to the underwriters upon completion of this offering at an exercise price equal to 125% of the public offering price per share.

Unless we specifically state otherwise, all information in this prospectus assumes:

- that all outstanding shares of our Series A preferred stock, Series B preferred stock and Series C preferred stock are converted into shares of our common stock prior to completion of this offering;
- that all outstanding warrants to purchase our common stock with an exercise price of $13.00 per share have been exchanged for our common stock based on an exchange rate of one share of common stock for every two shares of common stock purchasable under such warrants in a cashless exchange. See the full discussion in “Related party transactions — Warrants to Purchase Common Stock”;
- no exercise of the underwriters’ over-allotment option;
- the adoption of our fourth amended and restated certificate of incorporation and third amended and restated bylaws; and
- a 1-for-2 reverse stock split of our common stock which became effective subsequent to June 30, 2005.

Summary financial data

The following summary financial data for the fiscal years ended December 31, 2002, 2003 and 2004 have been derived from our historical audited financial statements. The summary financial data for the six month periods ended June 30, 2004 and 2005 have been derived from our unaudited financial statements. The unaudited summary financial data include, in our opinion, all adjustments, consisting only of normal, recurring adjustments, necessary to present fairly the financial position and results of operations for the periods presented. Our historical results for any prior or interim period are not necessarily indicative of results to be expected for a full fiscal year or for any future period. The summary financial data shown below account for the revenues and related expenses for our DIFOTI® product, a non-invasive imaging device for the detection of dental cavities, as a discontinued operation. We decided to discontinue all operations associated with our DIFOTI® product, effective as of April 5, 2005, in order to focus our resources on the development and commercialization of MelaFind®. See the footnote to the Financial Statements relating to discontinued operations and assets held for sale included elsewhere in this prospectus. You should read this information together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's discussion and analysis of financial condition and results of operations" section of this prospectus.

(in thousands, except share and per share data)	Year ended December 31,			Six months ended June 30,	
	2002	2003	2004	2004	2005
				(unaudited)	
Statement of Operations Data:					
Revenue from grants	$ 547	$ —	$ —	$ —	$ —
Operating expenses:					
Cost of grant revenue	564	—	—	—	—
General and administrative expenses	511	1,034	1,234	639	996
Research and development	404	828	1,892	693	1,546
Operating loss from continuing operations	(932)	(1,862)	(3,126)	(1,332)	(2,542)
Interest (income)/expense	8	76	67	82	(63)
Loss from continuing operations	(940)	(1,938)	(3,193)	(1,414)	(2,479)
Loss from discontinued operations	(201)	(12)	(426)	(102)	(330)
Net loss	(1,141)	(1,950)	(3,619)	(1,516)	(2,809)
Preferred stock deemed dividends	214	322	676	243	719
Preferred stock accretion	180	25	258	25	647
Stock distribution of preferred Series B shares	—	102	—	—	—
Net loss attributable to common stockholders	$ (1,535)	$ (2,399)	$ (4,553)	$ (1,784)	$ (4,175)
Net loss per share, basic and diluted:					
Continuing operations	$ (0.87)	$ (1.48)	$ (2.34)	$ (0.98)	$ (2.13)
Discontinued operations	(0.13)	(0.01)	(0.24)	(0.06)	(0.18)
Basic and diluted net loss per common share	$ (1.00)	$ (1.49)	$ (2.58)	$ (1.04)	$ (2.31)
Basic and diluted weighted average number of shares outstanding	1,534,760	1,614,897	1,766,608	1,722,743	1,809,758
Pro forma basic and diluted loss from continuing operations per common share (unaudited)(1)			$ (0.80)		$ (0.38)
Pro forma basic and diluted weighted average number of common shares outstanding (unaudited)(1)			3,967,024		6,513,164

(1) Pro forma basic and diluted loss from continuing operations per common share reflects the effect of the assumed conversion of our preferred stock, as if this offering had occurred at the date of original issuance into 3,398,105 shares of our common stock for the year ended December 31, 2004 and six months ended June 30, 2005 which will occur upon closing of this public offering. Additionally, it is assumed that 2,610,643 warrants to purchase the company's common stock will be exchanged for a total of 1,305,321 shares of our common stock based on an exchange ratio of one share of our common stock for every two shares of our common stock purchasable under the warrants and will occur prior to the closing of this offering. The loss from continuing operations used in the computation of unaudited pro forma basic and diluted loss from continuing operations per share, has been adjusted to reverse the accretion on our preferred stock and also excludes the preferred stock dividends for the respective period.

The following table presents summary balance sheet data, derived from our historical audited financial statements, as of December 31, 2003 and December 31, 2004. The table also presents summary balance sheet data, derived from our historical unaudited financial statements, as of June 30, 2005:

- On an actual basis; and
- On an as adjusted basis to give effect to (1) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,398,105 shares of common stock upon the completion of this offering; (2) the exchange of 2,610,643 warrants to purchase the company's common stock for a total of 1,305,321 shares of our common stock based on an exchange ratio of one share of our common stock for every two shares of our common stock purchaseable under the warrants which has occurred; and (3) the sale of 4,000,000 shares of common stock in this offering based on the initial public offering price of $5.00 per share, after deducting estimated underwriting discounts and commissions and offering expenses paid and payable by us.

(in thousands)	As of December 31,		As of June 30, 2005	
	2003	2004		
	Actual	Actual	Actual	Pro forma as adjusted
			(unaudited)	
Balance sheet data:				
Cash, cash equivalents and marketable securities	$ 117	$ 6,703	$ 3,794	$ 20,314
Working capital	(433)	6,122	3,480	20,000
Total assets	432	7,096	4,997	21,517
Total liabilities	650	691	1,245	1,245
Redeemable convertible preferred stock	4,067	9,955	10,602	—
Total stockholders' (deficiency)/equity	(4,285)	(3,550)	(6,850)	$ 20,272

Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this prospectus, before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition and results of operations would suffer. In that case, the trading price of our common stock would likely decline and you might lose all or part of your investment in our 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 five years in developing MelaFind®. MelaFind® will require additional development, clinical evaluation, regulatory approval, significant marketing efforts and substantial additional investment before it can provide us with any revenue. Our efforts may not lead to commercially successful products for a number of reasons, including:

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

We do not expect to be able to commercialize MelaFind® before 2007. If we are unable to develop, 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 US or in any foreign market. We have not filed, and currently do not have plans to file, for regulatory approval in any foreign market. We plan initially to launch MelaFind®, once approved, in the US. The regulatory approval process for MelaFind® in the US involves, among other things, successfully completing clinical trials and obtaining PMA approval from the FDA. We commenced the PMA application process for MelaFind® by filing a proposed outline for a Modular PMA application (a compilation of well-delineated components submitted separately) on September 30, 2002. 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. Before submitting a PMA application (the final module), we must successfully complete a pivotal clinical trial to demonstrate that MelaFind® is safe and effective. Product development, including clinical trials, is a long, expensive and uncertain process, and is subject to delays and failure at any stage. Furthermore, the data obtained from the trial may be inadequate to support approval of a PMA application. While we obtained a Protocol Agreement from the FDA, FDA approval of a Protocol Agreement does not mean that the FDA will consider the data gathered in the trial sufficient to support approval of a PMA application, even if the trial's intended endpoints are achieved. There may be unexpected findings, particularly those that may only become evident from the larger scale of the pivotal clinical trial, as compared with the smaller scale tests done to date. For example, we initiated a clinical trial and encountered several technical problems which required us to refine the MelaFind® system. The data obtained in the pivotal trial may not be sufficient to support the anticipated indication for use, and may not support a more limited indication for use. The occurrence of unexpected findings in connection with the pivotal trial or any subsequent clinical trial required by the FDA may prevent or delay obtaining PMA approval, and may adversely affect coverage or reimbursement determinations. The FDA may also 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. If we are unable to complete the clinical trials necessary to successfully support the MelaFind® PMA application, our ability to commercialize MelaFind®, and our business, financial condition, and results of operations would be materially adversely affected, thereby threatening our ability to continue operations.

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

Even if approved, MelaFind® may not be approved for the indications that are necessary or desirable for successful commercialization. Our preference is to obtain a broad indication for use in diagnosing 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 should 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 US 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 payors. 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 US, 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 payors.

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 payors 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 payors 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 payors 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 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 US 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.

Any adverse results in our clinical trials, or difficulties in conducting our clinical trials, could have a material adverse effect on our business.

Clinical studies in the US have been ongoing for over five years, and we have a Protocol Agreement with the FDA, but we have not conducted the pivotal clinical trial required for PMA approval. We initiated a trial under the terms of the Protocol Agreement at the end of 2004. However, technical operational issues with the systems were experienced, requiring further refinement. We are currently refining the hardware systems and expect to have new systems available in order to start the pivotal clinical trial in early 2006. However, we cannot provide any assurances that we will have these systems available on a timely basis. In addition, the pivotal clinical trial and supporting clinical studies will require the involvement of larger numbers of clinical sites than we have previously engaged at any single time, and the recruitment of large numbers of patients. If the clinical sites, which enroll patients on a best efforts basis, do not provide cases at rates anticipated for any reason (such as, for example, lower than forecasted clinical site productivity), we may face delays or may be unable to complete the development of MelaFind®.

Risk of delay in product development.

We could encounter delays in our pivotal trial or in obtaining PMA approval because of a number of factors. We will require the receipt of all information specified in our Protocol Agreement on the required number of melanomas before the pivotal clinical trial can be concluded. The MelaFind® classifier will then be utilized to evaluate the lesions acquired

during the pivotal trial, and the results will be analyzed to determine if we have achieved the endpoints specified in the Protocol Agreement.

The final training of the classifier, required to be completed before the classifier is utilized as described above, is expected to take approximately two months. Accordingly, the classifier must be ready for final training two months before the end of the pivotal trial. For the classifier to be ready for final training, approximately 300 melanoma lesions are targeted to have been received. Therefore, in addition to acquiring the melanoma lesions required to complete the pivotal trial (approximately 100), we must have completed the acquisition of approximately 300 training melanoma lesions on schedule. Currently, approximately 268 melanoma lesions are in the training database. The current classifier has been trained on 113 of these melanoma lesions.

Our schedule for the acquisition of these lesions is based upon the projected numbers of imaging devices to be located at participating sites, the projected productivity of those sites in terms of melanomas and other lesions biopsied per month, and the projected efficiency of the study pathologists in classifying the lesion slides presented for histological analysis (the microscopic examination of excised or biopsied tissue specimens) and reporting their results. If we are unable to produce and maintain a sufficient number of imaging devices at participating sites, if the clinicians do not maintain sufficient productivity, or if the pathologists do not produce reports with sufficient efficiency, then our ability to maintain our schedule will be adversely affected, the start or conclusion of the pivotal trial may be delayed, and the submission of the completed PMA will be delayed.

To date, the lesion images in the training database have been acquired using first-generation hand-held devices, which also extract data from the lesions that are used by the classifiers. Pre-commercialization hand-held devices are being developed for use in the pivotal trial. If the lesion data obtained with pre-commercialization devices are not consistent with data from the first generation hand-held devices, the classifier will need to be trained solely on lesions imaged using only one or the other generation of hand-held devices. Were this need to arise, significant delay and expense could be incurred, which could jeopardize our ability to complete the development of MelaFind®.

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 US government agencies, on classified projects. We have financed our operations since 1999 primarily through private placements of our equity securities, and have devoted substantially all of our resources to research and development relating to MelaFind®. Our net loss for the six months ended June 30, 2005 was $2.8 million, and as of June 30, 2005, we had an accumulated deficit of approximately $16.7 million. We expect our research and development expenses 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, if we complete our initial public offering, we expect that our general and administrative expenses will increase due to the additional operational and regulatory burdens 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.; LINOS Photonics, Inc.; and Biomips Engineering. 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: 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 payors;
- 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, and molecular and genetic screening tests. 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.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials 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.

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®. 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®.

In addition to the foregoing, our clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, 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 payors to reduce or limit the growth of healthcare costs, the increasing influence of health maintenance organizations, and additional legislative proposals to reduce or limit increase in public funding for healthcare services. Private payors, including managed care payors, 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 payors are expected to continue. Payors 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 US, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed healthcare in the US and proposed legislation intended to control the cost of publicly funded healthcare programs could significantly influence the purchase of healthcare services and products, and may force us to reduce prices for MelaFind® or result in the exclusion of MelaFind® from reimbursement programs.

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®. If MelaFind® receives the appropriate regulatory approvals but does not achieve an adequate level of

acceptance by patients, physicians and healthcare payors, 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 the 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 identification and screening of melanomas is now dominated by visual clinical evaluation, with a minority of dermatologists using dermoscopy. Even if MelaFind® proves to be as effective as visual inspection by an expert dermatologist, and if all approvals are obtained, 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®, and 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.

We currently believe that our available cash, cash equivalents and marketable securities, together with our net proceeds from this offering, will be sufficient to fund our anticipated levels of operations through mid 2007. However, our operations have consumed substantial amounts of cash for each of the last six years. We expect to continue to spend substantial amounts on research and development, including conducting a clinical trial for MelaFind®. We will need additional funds to fully commercialize the product, including development of a direct sales force and expansion of manufacturing capacity. We expect that our cash used by operations will increase significantly in each of the next several years, and should we encounter any material delays or impediments, we may need additional funds to complete the development of MelaFind® and commence commercialization of MelaFind® and we will need additional funds to achieve significant commercialization of MelaFind®. Any additional financing may be dilutive to stockholders, or may

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

- the schedule, costs, and results of our 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 payors, or the amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind®;
- the cost of commercialization activities, including 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 market MelaFind® in the US, 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 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 US 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 US, 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 not yet completed the development and testing of MelaFind®, and as a result 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 manufacturing capacity by a significant factor over the current level, or procure manufacturing services from others. 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 plan to outsource certain production aspects 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, if we enter into contracts for 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 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, if 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 FillFactory, a subsidiary of Cypress Semiconductor Corp., to manufacture and supply the complementary metal oxide semiconductor sensor in MelaFind®, on Pracownia Optyki Instrumentalnej (Optyka) for lens elements, on ASKION GmbH (ASKION) for the main subassembly and on Fairchild Semiconductor Corp., Panasonic Corp., and others for light-emitting diodes, or LEDs, printed circuit boards, and other elements or components of our devices. We have written agreements with several of these vendors, under which the vendor is obligated to perform services or produce components for us. There can be no assurance that these third parties will meet their obligations under the agreements. 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 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 affect 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 GmbH (ASKION) to complete developmental engineering and testing of our hand-held imaging device, and have entered into a non-binding Letter of Intent with ASKION to assemble the components and produce initial quantities of our hand-held imaging devices for clinical trials. We intend to enter into a contract for commercial production of the hand-held imaging devices once 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 intend to enter into contracts with Carl Zeiss Jena GmbH for development and commercial production of lenses. These lenses are currently assembled by ourselves utilizing the lens elements produced by Optyka; the manufacturing agreement with ASKION will include integration of these 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 Carl Zeiss Jena GmbH, 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 pivotal clinical trial and/or 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 US 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® in 2007.

Assuming that regulatory approval of MelaFind® is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or effectiveness of the device. Later discovery of previously unknown problems with MelaFind®, including manufacturing problems, or failure to comply with regulatory requirements such as the Quality System Regulation (a set of current good manufacturing practice requirements put forth by the FDA which govern the methods

used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation and servicing of finished devices) (QSR), may result in restrictions on MelaFind® or its manufacturing processes, withdrawal of MelaFind® from the market, patient or physician notification, voluntary or mandatory recalls, fines, withdrawal of regulatory approvals, refusal to approve pending applications or supplements to approved applications, refusal to permit the import or export of our products, product seizures, injunctions or the imposition of civil or criminal penalties. Should any of these enforcement actions occur, our business, financial condition and results of operations could be materially and adversely affected.

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continuous review and periodic inspections by the FDA and other regulatory bodies. In particular, we and our suppliers are required to comply with the QSR and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, promotion, distribution, and shipping of MelaFind®, and with record keeping practices. We also will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports and registration and listing requirements. To the extent that we contract with third parties to manufacture some of our products, our manufacturers will be required to adhere to current Good Manufacturing Practices (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. However, we were previously inspected in connection with DIFOTI®, which we have discontinued for business reasons, and were cited for failures to comply fully with QSR mandated procedures. The FDA inspectors observed deficiencies that were documented on FDA Form 483 that was issued to us following the inspection. We have discussed the findings in a subsequent meeting with the FDA and are in the process of addressing the deficiencies. We are working with consultants to address the inspectional findings, particularly as they relate to current MelaFind® design development and ultimate MelaFind® commercial manufacturing. If we are not successful in convincing the FDA that we are capable of addressing its concerns, or if our efforts to address the deficiencies should prove unsuccessful, we might 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 US Congress that could significantly change the statutory provisions governing the approval, manufacture and marketing of a medical device. Additionally, healthcare is heavily regulated by the federal government, and by state and local governments. The federal laws and regulations affecting healthcare change constantly, thereby increasing the uncertainty and risk associated with any healthcare related venture, including our business and MelaFind®. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

The federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Food, Drug, and Cosmetic Act (FD&C 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 US. The clinical studies of MelaFind® are considered by the FDA as Non-Significant Risk (NSR). Consequently, the trials are conducted under the auspices of an abbreviated Investigational Device Exemption (IDE). We therefore do not maintain domestic clinical trial liability insurance. 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, or any interruption in the ability of physicians to obtain access to our MelaFind® server and its database could adversely impact our business, financial condition and results of operations.

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.

The connection between the MelaFind® hand-held imaging device and the central server in our offices will be dependent on the internet. Our success will depend in large part on the continued availability of electronic means for storing and transmitting encoded compressed diagnostic information, and storing and transmitting the results of the comparison of such information with our electronically-maintained database through the internet. If the domestic and international telecommunications infrastructure required for these transmissions fails, our business could be materially adversely affected.

We plan to use the internet as a medium to provide diagnostic assistance 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 is 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, provision for off-site manufacturing, 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 destroy our manufacturing equipment or inventory, and 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 US, we may market MelaFind® internationally. Outside the US, 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 US 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 Gutkowicz-Krusin, Ph.D., our Director of Clinical Studies. Our success will depend on our ability to retain our current 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 may be adversely affected by changes required by financial and accounting regulatory agencies.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the US. Generally accepted accounting principles in the US are subject to interpretation by the Financial Accounting Standards Board (FASB), the American Institute of Certified Public Accountants, the Securities and Exchange Commission (SEC), and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

For example, we currently are not required to record stock-based compensation charges if the employee's stock option exercise price is equal to or exceeds the fair value of our common stock at the date of grant. However, several companies have recently elected to change their accounting policies, and have begun to record the fair value of stock options as an expense. New FASB Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (FASB Statement No. 123R), requires companies to recognize in the income statement the grant-date fair value of stock options and other equity-based compensation issued to employees. Under FASB Statement No. 123R, SEC registrants would have been required to implement this standard for interim or annual periods beginning after June 15, 2005, or after December 15, 2005 for small business issuers. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for FASB Statement No. 123R. The SEC's new rule permits companies to implement FASB Statement No. 123R at the beginning of their next fiscal year, instead of the next reporting period that begins after June 15, 2005, or December 15, 2005 for small business issuers. Awards to most non-employee directors will be accounted for as employee awards. All public companies must use either the modified prospective or the modified retrospective transition method. Under the modified prospective method, awards that are granted, modified, or settled after the date of adoption should be measured and accounted for in accordance with FASB Statement No. 123R. Under the modified retrospective method, the previously-reported amounts are restated to either the beginning of the year of adoption or for all periods presented. If we elect to adopt the retroactive provisions and to restate all prior periods presented our operating expenses and reported losses will increase. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

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 then current fair market value of our common stock underlying the options which vest when the milestone is attained. Assuming that all shares offered are sold in this public offering at a price of $5.00 per share, and that upon the attainment of each of the relevant milestones such offering price remains the fair market value per share of our common stock, and that the number of shares of our common stock outstanding after this offering remains 10,513,164 then we will record a compensation expense: (1) upon completion of this offering of $551,570 with respect to 125,000 shares underlying options with an exercise price of $0.46 per share; (2) upon filing our MelaFind® PMA with

the FDA of $227,000 with respect to 50,000 shares underlying options with an exercise price of $0.46 per share; and (3) upon our receipt of PMA approval for MelaFind® of $228,000 with respect to 50,000 shares underlying options with a weighted average exercise price of $0.44 per share and of $1,758,643 with respect to 387,366 shares underlying options with an exercise price of $0.46 per share.

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 and provide accurate financial statements could cause our stock price to decrease substantially.

We will face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 (SOX), as well as new rules subsequently implemented by the SEC, the Public Company Accounting Oversight Board and the NASDAQ Capital Market, require changes in the corporate governance practices of public companies. We expect these new rules and regulations to increase our legal and financial compliance costs, to divert management attention from operations and strategic opportunities, and to make legal, accounting and administrative activities more time-consuming and costly. We also expect to incur substantially higher costs to maintain directors' and officers' insurance. We are in the process of instituting changes to our internal procedures to satisfy the requirements of the SOX. We are evaluating our internal controls 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. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 of the SOX in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations, since there is no precedent available by which to measure compliance adequacy. As a small company with limited capital and human resources, we will need to divert management's time and attention away from our business in order to ensure compliance with these regulatory requirements. As a public company, we will require greater financial resources than we have had as a private company. Implementing these changes may require new information technologies systems, the auditing of our internal controls, and compliance training for our directors, officers and personnel. Such efforts would require a potentially 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 provide accurate financial statements and comply with the SOX. Any failure to maintain the adequacy of our internal controls and provide accurate financial statements could cause the trading price of our common stock to decrease substantially.

Risks Relating to this Offering

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for quotation on the NASDAQ Capital Market, subject to official notice of issuance, an active trading market for our shares may never develop or be sustained following this offering. Further, we cannot be certain that the market price of our common stock will not decline below the initial public offering price or 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. The initial public offering price for our common stock will be determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering and investors may therefore be unable to sell their common stock at or above the initial public offering price.

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

Our stock price is likely to be volatile. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial

public offering price. 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 US and other countries;
- changes in accounting principles or practices;
- general economic, industry and market conditions; and
- future sales of our common stock.

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

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in “Use of proceeds.” Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds, with only limited information concerning management’s specific intentions. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business and financial condition. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Concentration of ownership among our directors, executive officers, and principal stockholders may prevent new investors from influencing significant corporate decisions.

Upon closing of this offering, based upon beneficial ownership as of August 31, 2005, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates will, in the aggregate, beneficially own approximately 28% of our outstanding common stock (which does not include any common stock purchased by such persons in this offering). As a result, these stockholders, subject to any fiduciary duties owed to our other stockholders under Delaware law, will 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.

If there are substantial sales of our common stock, our stock price could decline.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that these sales may occur, the market price of our common stock could decline. Based on shares outstanding on August 31, 2005, upon the closing of this offering, assuming no outstanding options are exercised prior to the closing of this offering, we will have approximately 10,513,164 shares of common stock outstanding. All of the shares offered under this prospectus will be freely tradable without restriction or further registration under the federal securities laws, unless purchased by our affiliates. Taking into consideration the effect of lock-up agreements that have been entered into by certain of our stockholders, we estimate that the remaining 6,513,164 shares of our common stock outstanding upon the closing of this initial public offering will be available for sale pursuant to Rule 144 and Rule 144(k), as follows:

- beginning on the effective date of this prospectus, in addition to the shares sold in the offering, approximately 1,229,577 of our restricted shares will be eligible for sale under Rule 144, of which approximately 408,402 shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144 and approximately 821,175 shares will be eligible for sale as unrestricted shares under Rule 144(k);
- beginning 270 days after the effective date of this prospectus, approximately 6,347,015 of our restricted shares will be eligible for sale under Rule 144 (which includes the 1,229,577 restricted shares referred to above), of which approximately 3,226,819 shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144 and approximately 3,120,196 shares will be eligible for sale as unrestricted shares under Rule 144(k); and
- beginning October 27, 2006, approximately an additional 166,149 of our restricted shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144.

Existing stockholders holding an aggregate of 5,090,001 shares of common stock (including shares of our common stock purchasable pursuant to warrants to purchase our common stock) based on shares outstanding as of August 31, 2005 have rights with respect to the registration of these shares of common stock with the SEC. See “Description of capital stock — Registration Rights.” If we register these shares of common stock, they can immediately sell those shares in the public market.

Within nine months following this offering, we intend to register up to 1,899,875 shares of common stock that are authorized for issuance under our stock option plans. As of August 31, 2005, 899,875 shares were subject to outstanding options, of which 446,675 shares were vested. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above and restrictions on our affiliates.

You will incur immediate and substantial dilution as a result of this offering.

The initial public offering price is substantially higher than the book value per share of our common stock. As a result, purchasers in this offering will experience immediate and substantial dilution of $3.07 per share in the tangible book value of our common stock from the initial public offering price, based on the number of shares outstanding as of June 30, 2005. This is due in large part to earlier investors in the company having paid substantially less than the initial public offering price when they purchased their shares. Investors who purchase shares of common stock in this offering will contribute approximately 50% of the total amount we have raised to fund our operations but will own only

approximately 38% of our common stock, based on the number of shares outstanding as of June 30, 2005. In addition, the exercise of currently outstanding options and warrants to purchase common stock and future equity issuances, including future public or private securities offerings and any additional shares issued in connection with acquisitions, will result in further dilution.

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

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

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

In addition, Section 203 of the Delaware General Corporation Law generally limits our ability to engage in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirors at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Special note regarding forward-looking statements

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations stated in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the “Risk factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Additional risks, uncertainties and factors, other than those discussed under “Risk factors,” could also cause our actual results to differ materially from those projected in any forward-looking statements we make. We operate in a very competitive and rapidly changing environment in which new risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update or revise any forward-looking statements, or to so update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Use of proceeds

We estimate that we will receive net proceeds of approximately $16.5 million from our sale of 4,000,000 shares of common stock based on the initial public offering price of $5.00 per share, after deducting underwriting discounts and commissions and estimated expenses of approximately $3.5 million, which includes our underwriter's non-accountable expense allowance, legal, accounting, printing costs and expenses, and various fees associated with the registration and listing of our securities payable by us. If the underwriters exercise their over-allotment option in full, we will receive an additional $2,790,000 after deducting $210,000 for underwriting discounts and commissions.

We intend to use these net proceeds approximately as follows:

- 78% ($12.8 million) to fund our research and development activities, including our clinical studies;
- 3% ($0.5 million) toward developing our sales and marketing capabilities; and
- 19% ($3.2 million) for general corporate purposes, including working capital, and capital expenditures made in the ordinary course of business.

The amounts that we actually expend for working capital purposes will vary significantly depending on a number of factors. As a result, we will retain broad discretion in the allocation of the net proceeds of this offering. While we have no present understandings, commitments or agreements to enter into any potential acquisitions, we may also use a portion of the net proceeds for the acquisition of, or investment in, technologies or products that complement our business. Pending the uses described above, we intend to invest the net proceeds of this offering in short-term, investment-grade, interest-bearing securities. We cannot predict whether the proceeds which we invest will yield a favorable return.

Dividend policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain our cash for the development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on then existing conditions, including our earnings, financial condition, results of operations, level of indebtedness, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our board of directors' ability to declare a dividend is also subject to limits imposed by Delaware law.

Capitalization

You should read this capitalization table together with the sections of this prospectus entitled “Management’s discussions and analysis of financial condition and results of operations” and with the financial statements and related notes to those statements included elsewhere in this prospectus.

The following table sets forth our capitalization as of June 30, 2005:

- on an actual basis; and
- on a pro forma as adjusted basis to reflect the conversion of all our outstanding shares of convertible preferred stock into shares of common stock prior to completion of this offering, the assumed conversion of 2,610,643 warrants to purchase the company’s common stock which have been exchanged for a total of 1,305,321 shares of the company’s common stock based on an exchange ratio of one share of our common stock for every two shares of our common stock purchasable under the warrants and the receipt of the estimated net proceeds from the sale of 4,000,000 shares of our common stock in this offering based on the initial public offering price of $5.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(in thousands, except share and per share data)	**As of June 30, 2005**	
	Actual	**Pro forma(1) as adjusted (unaudited)**
Redeemable Convertible Preferred Stock:		
Redeemable Preferred Stock Series B convertible; 992,986 shares designated (liquidation preference $2.26 per share); issued and outstanding 992,986 shares at December 31, 2003 and 2004 and June 30, 2005 and 0 shares at June 30, 2005, pro forma as adjusted	$ 2,244	—
Redeemable Preferred Stock Series C convertible 5,744,340 shares designated (liquidation preference $2.26 per share); issued and outstanding 907,077 shares at December 31, 2003 and 5,414,779 shares at December 31, 2004 and June 30, 2005 and 0 shares at June 30, 2005, pro forma as adjusted	8,358	—
Stockholders’ (Deficiency) Equity:		
Preferred stock — $.10 par value; authorized 16,936,704 shares:		
Series A Convertible Preferred Stock, 199,380 shares designated (liquidation preference $5.00 per share); issued and outstanding 198,000 shares at December 31, 2003 and 2004 and June 30, 2005 and 0 shares at June 30, 2005, pro forma as adjusted	972	—
Common stock — $.001 par value; authorized 30,000,000 shares; issued and outstanding 1,684,760 shares at December 31, 2003 and 1,809,758 shares at December 31, 2004 and June 30, 2005 and 10,513,164 shares at June 30, 2005, pro forma as adjusted	2	10
Additional paid-in capital	9,035	37,121
Deferred compensation	(143)	(143)
Accumulated deficit	(16,716)	(16,716)
Stockholders’ (Deficiency) Equity	(6,850)	20,272
Total Capitalization	$ 3,752	$ 20,272

None of the columns shown above reflect the following:

- 899,875 shares of common stock issuable as of the date of this prospectus upon the exercise of outstanding stock options under our 2003 Stock Incentive Plan and our 1996 Stock Option Plan, respectively, at a weighted average exercise price of approximately $0.64 per share;

- up to 1,000,000 shares of common stock reserved for future grants under our 2005 Stock Incentive Plan;
- 75,000 shares of common stock issuable upon exercise of outstanding warrants to purchase our common stock at an exercise price of $7.00 per share;
- 73,280 shares of common stock issuable upon exercise of outstanding warrants to purchase our Series C preferred stock (assuming conversion of our Series C preferred stock) at an exercise price of $4.52 per share; and
- 150,000 shares of common stock issuable upon exercise of warrants to be issued to the underwriters upon completion of this offering at an exercise price equal to 125% of the public offering price per share.

(1) Excludes the impact of 125,000 options that vest upon consummation of the offering, which will have no effect on total stockholders' equity but will require an expense of $551,570 to be recorded if such options vested based on the initial public offering price of $5.00 per share.

Dilution

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the net tangible book value per share of our common stock immediately after this offering. Net tangible book value per share represents the amount of our common stockholders' equity, less intangible assets, divided by the number of shares of our common stock outstanding. As of June 30, 2005, we had a net tangible book value of approximately $(6,849,911) or $(3.78) per share of common stock. Pro forma net tangible book value as of June 30, 2005 is $3,751,758 or $0.58 per common share. After giving effect to the issuance and sale by us of 4,000,000 shares of common stock offered in this offering based on the initial public offering price of $5.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses, our as adjusted pro forma net tangible book value as of June 30, 2005, would have been $20,271,758, or $1.93 per share of common stock. This represents an immediate increase in pro forma net tangible book value of $1.35 per share of common stock to our existing stockholders and an immediate dilution of $3.07 per share to the new investors purchasing shares in this offering. The following table illustrates this per share dilution:

Initial public offering price per share	$	5.00
Net tangible book value per share as of June 30, 2005	$	(3.78)
Pro forma net tangible book value per share as of June 30, 2005	$	0.58
Increase in pro forma net tangible book value per share attributable to existing investors	$	1.35
Pro forma net tangible book value per share after the offering	$	1.93
Dilution per share to new investors	$	3.07

The following table sets forth on a pro forma as adjusted basis, as of June 30, 2005, the number of shares of common stock purchased from us (assuming conversion of all preferred stock into common stock), the total consideration paid and the average price per share paid by existing holders of common stock (assuming conversion of all preferred stock into common stock) and by the new investors in this initial public offering, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares purchased		Total consideration		Average consideration
	Number	Percent	Amount	Percent	Per share
Existing Investors	6,513,164	62.0%	$ 20,033,573	50.0%	$ 3.08
New Investors	4,000,000	38.0%	20,000,000	50.0%	5.00
Total	10,513,164	100.0%	$ 40,033,573	100.0%	

Assuming all our outstanding options and the outstanding warrants are fully exercised, the shares purchased by the new investors would constitute 34.6% of all shares purchased from us, and the total consideration paid by new investors would constitute 48.2% of the total consideration paid for all shares purchased from us. In addition, the average price per share paid by new investors would be $5.00, and the average price per share paid by existing stockholders would be $2.84.

If the underwriters exercise their over-allotment in full, the following will occur:

- The pro forma as adjusted percentage of shares of our common stock held by existing stockholders will decrease to approximately 58.6% of the total number of pro forma as adjusted shares of our common stock outstanding after this offering; and
- The pro forma as adjusted number of shares of our common stock held by new public investors will increase to 4,600,000, or approximately 41.4% of the total pro forma as adjusted number of shares of our common stock outstanding after this offering.

In addition, upon completion of this offering, the underwriters will receive warrants to purchase up to an aggregate of 150,000 shares of our common stock at an exercise price equal to 125% of the public offering price per share. The

warrants will be exercisable commencing on the first anniversary of the date of this prospectus and ending on the fifth anniversary of the date of this prospectus.

In the preceding tables, the shares of our common stock exclude, as of June 30, 2005:

- 899,875 shares of common stock issuable as of the date of this prospectus upon the exercise of outstanding stock options under our 2003 Stock Incentive Plan and our 1996 Stock Option Plan, respectively, at a weighted average exercise price of approximately $0.64 per share;
- up to 1,000,000 shares of common stock reserved for future grants under our 2005 Stock Incentive Plan;
- 75,000 shares of common stock issuable upon exercise of outstanding warrants to purchase common stock at an exercise price of $7.00 per share; and
- 73,280 shares of common stock issuable upon exercise of outstanding warrants to purchase our Series C preferred stock (assuming conversion of our Series C preferred stock) at an exercise price of $4.52 per share; and
- 150,000 shares of common stock issuable upon exercise of warrants to be issued to the underwriters upon completion of this offering at an exercise price equal to 125% of the public offering price per share.

Selected financial data

The following summary financial data for the fiscal years ended December 31, 2000, 2001, 2002, 2003 and 2004 have been derived from our historical audited financial statements. The summary financial data for the six months periods ended June 30, 2004 and 2005 have been derived from our unaudited financial statements. The unaudited summary financial data include, in our opinion, all adjustments, consisting only of normal, recurring adjustments, necessary to present fairly the financial position and results of operations for the periods presented. Our historical results for and prior or interim period are not necessarily indicative of results to be expected for a full fiscal year or for any future period. The selected financial data shown below accounts for the revenues and related expenses for our DIFOTI® product, a non-invasive imaging device for the detection of dental cavities, as a discontinued operation. We decided to discontinue all operations associated with our DIFOTI® product, effective as of April 5, 2005, in order to focus our resources and attention on the development and commercialization of MelaFind®. See the footnote to the Financial Statements relating to discontinued operations and assets held for sale included elsewhere in this prospectus. You should read the following selected financial information together with the financial statements and the related notes appearing at the end of this prospectus and the "Management's discussion and analysis of financial condition and results of operations" section of this prospectus.

(in thousands, except share and per share data)	Year ended December 31,					Six months ended June 30,	
	2000	2001	2002	2003	2004	2004	2005
						(unaudited)	
Statements of Operations Data:							
Revenue from grants	$ 210	$ 290	$ 547	$ —	$ —	$ —	$ —
Cost of grant revenue	248	193	564	—	—	—	—
General and administrative expenses	1,061	2,563	511	1,034	1,234	639	996
Research and development	726	144	404	828	1,892	693	1,546
Operating loss from continuing operations	(1,825)	(2,610)	(932)	(1,862)	(3,126)	(1,332)	(2,542)
Interest (income)/expense	(79)	(85)	8	76	67	82	(63)
Loss from continuing operations	(1,746)	(2,525)	(940)	(1,938)	(3,193)	(1,414)	(2,479)
Loss from discontinued operations	(534)	(343)	(201)	(12)	(426)	(102)	(330)
Net loss	(2,280)	(2,868)	(1,141)	(1,950)	(3,619)	(1,516)	(2,809)
Preferred stock deemed dividends	85	213	214	322	676	243	719
Preferred stock accretion	143	180	180	25	258	25	647
Stock distribution of preferred Series B shares	—	—	—	102	—	—	—
Net loss attributable to common stockholders	$ (2,508)	$ (3,261)	$ (1,535)	$ (2,399)	$ (4,553)	$ (1,784)	$ (4,175)
Net loss per share, basic and diluted:							
Continuing operations	$ (1.29)	$ (1.90)	$ (0.87)	$ (1.48)	$ (2.34)	$ (0.98)	$ (2.13)
Discontinued operations	(0.35)	(0.23)	(0.13)	(0.01)	(0.24)	(0.06)	(0.18)
Basic and diluted net loss per common share	$ $(1.64)	$ (2.13)	$ (1.00)	$ (1.49)	$ (2.58)	$ (1.04)	$ (2.31)
Basic and diluted weighted average number of shares outstanding	1,529,471	1,534,760	1,534,760	1,614,897	1,766,608	1,722,743	1,809,758
Pro forma basic and diluted loss from continuing operations per common share (unaudited)(1)					$ (0.80)		$ (0.38)
Pro forma basic and diluted weighted average number of common shares outstanding (unaudited)(1)					3,967,024		6,513,164

(1) Pro forma basic and diluted loss from continuing operations per common share reflects the effect of the assumed conversion of the company's preferred stock, as if this offering had occurred at the date of original issuance, into 3,398,105 shares of our common stock for the year ended December 31, 2004 and six months ended June 30, 2005 which will occur upon closing of this offering. Additionally, it is assumed that 2,610,643 warrants to purchase

the Company's common stock will be exchanged for a total of 1,305,321 shares of the company's common stock based on an exchange ratio of one share of our common stock for every two shares of our common stock purchaseable under the warrants and will occur prior to the closing of this offering. The loss from continuing operations used in the computation of unaudited pro forma basic and diluted loss from continuing operations per share has been adjusted to reverse the accretion on our preferred stock and also excludes the preferred stock dividends for the respective period.

The following table presents summary balance sheet data, derived from our historical audited financial statements. The table also presents summary balance sheet, derived from our historical unaudited financial statements, as of June 30, 2004 and June 30, 2005:

(in thousands, except share and per share data)	As of December 31,					As of June 30,	
	2000	2001	2002	2003	2004	2004	2005
						(unaudited)	
Balance Sheet Data:							
Total current assets	$ 3,513	$ 867	$ 111	$ 217	$ 6,813	$ 877	$ 4,726
Total assets	3,814	1,131	344	432	7,096	1,086	4,997
Total liabilities	211	247	529	650	691	1,571	1,246
Redeemable convertible preferred stock	2,058	2,155	2,244	4,067	9,955	5,167	10,602
Accumulated deficit	(4,148)	(7,197)	(8,518)	(10,288)	(13,907)	(11,804)	(16,716)
Total stockholders' (deficiency)/equity	(498)	(3,408)	(4,657)	(4,285)	(3,550)	(5,652)	(6,850)

Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a medical device company focused on the design and development 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 multiple wavelengths of light to capture images of suspicious pigmented skin lesions and extract data. We currently do not have any commercialized products or any significant source of revenue; however, the financial results for all periods discussed below account for the revenues and the related expenses associated with our DIFOTI® product, a non-invasive imaging device for the detection of dental cavities, as a discontinued operation. We decided to discontinue all operations associated with our DIFOTI® product effective as of April 5, 2005, in order to focus our resources and attention on the development and commercialization of MelaFind®. We are currently seeking an acquirer for the DIFOTI® assets, and we do not expect to have any significant continuing responsibility for the DIFOTI® business after its disposition. Unless otherwise indicated, the following discussion relates to our continuing operations.

Our revenue for the foreseeable future will depend on the commercialization of MelaFind® and may vary substantially from year to year and quarter to quarter. Our operating expenses may also vary substantially from year to year and quarter to quarter based on the timing of the clinical trial and patient enrollment. We believe that period-to-period comparisons of our results of operations are not meaningful and should not be relied on as indicative of our future performance.

We commenced operations in December 1989 as a New York corporation and re-incorporated as a Delaware corporation in September 1997. Since our inception, we have generated significant losses. As of June 30, 2005, we had an accumulated deficit of $16.7 million. We expect to continue to spend significant amounts on the development of MelaFind®. We expect to incur significant commercialization costs when we begin to introduce MelaFind® into the US market. We will need to raise additional funds in order to achieve significant commercialization of MelaFind® and generate significant revenues.

Most of our expenditures to date have been for research and development activities and general and administrative expenses. Research and development expenses represent costs incurred for product development, clinical trials and activities relating to regulatory filings and manufacturing development efforts. We expense all of our research and development costs as they are incurred.

Our research and development expenses incurred through June 30, 2005 were expenses related primarily to the development of MelaFind®. We expect to incur additional research and development expenses relating to MelaFind® prior to its commercial launch in the US and selected markets outside the US. These additional expenses are subject to the risks and uncertainties associated with clinical trials and the FDA regulatory review and approval process. As a result, these additional expenses could exceed our estimated amounts, possibly materially.

General and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with our efforts to obtain PMA approval for MelaFind® and toward development of a commercial infrastructure to market and sell MelaFind®. We anticipate that general and administrative expenses will increase as a result of the expected expansion of our operations, facilities and other activities associated with the planned expansion of our business, together with the additional costs associated with operating as a public company. We expect selling, general

and administrative expenses to increase as we build our sales force and marketing capabilities to support placing MelaFind® in selected markets.

At December 31, 2004 and June 30, 2005, we had available a net operating loss carry forward for federal income tax reporting purposes of approximately $12.2 million and $15.0 million, respectively. The net operating loss carry forward may be available to offset future taxable income expiring at various dates through the year 2025. The Company's ability to utilize its net operating losses may be significantly limited due to changes in the company's ownership as defined by federal income tax regulations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the US. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our judgments related to accounting estimates. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our financial statements appearing at the end of this prospectus, we believe that the following accounting policies and significant judgments and estimates relating to revenue recognition, stock-based compensation charges, and accrued expenses are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

We decided to discontinue all operations associated with our DIFOTI® product effective as of April 5, 2005, and account for the DIFOTI® revenue and expenses as a discontinued operation. Revenue from the DIFOTI® product sales had been recognized at the time of delivery and acceptance, after consideration of all the terms and conditions of the customer contract. The DIFOTI® products which were being sold prior to December 31, 2004 included a 30-day return policy. Revenue on these products was recognized after the shipment was made and the 30-day return period had elapsed. DIFOTI® products sold subsequent to December 31, 2004 were sold without a right of return and revenue was therefore recognized after the shipment was made. Deferred revenues at each respective balance sheet date consisted of revenues that were billed or paid in advance of the shipment of the product.

We currently do not have any commercialized products or any significant source of revenue.

Stock-Based Compensation

We account for non-employee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments issued in accordance with the Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services."

We account for stock-based compensation to employees under the intrinsic-value-based method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and disclose the effect of the differences which would result had we applied the fair-value-based method of accounting, on a pro forma basis, as required by FASB Statement No. 123, "Accounting for Stock-Based Compensation, as amended by Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure." In December 2004, FASB issued FASB Statement No. 123R, which addresses the accounting for share-based awards to employees and requires companies to recognize the fair value of stock options and other stock-based compensation to employees in their statement of operations. Because we currently account for our stock-based

compensation plans in accordance with APB Opinion No. 25, the adoption of FASB Statement No. 123R will have a material effect on our financial statements in future accounting periods.

Our common stock has not been publicly traded and the determination of the fair value of our common stock involves considerable judgment. In making this determination, we evaluated, among other things, our common stock transactions, the pricing of private equity sales, the rights and preferences of the security being valued, current market conditions, and company specific operational milestones.

During the twelve months ended June 30, 2005, we used two different fair values for our common stock in determining recorded compensation expense for stock options and warrants granted to employees, non-employee directors, and consultants. For the period July 2004 through September 2004, the fair value of our common stock as determined by management took into consideration market, income, and asset based approaches to valuation as set forth in the AICPA Audit and Accounting Practice Aid for "Valuation of Privately Held Company Equity Securities Issued as Compensation." We relied most heavily on the income approach utilizing a discounted cash flow method and also utilized the value derived from the market approach. The weighted value range of our common stock for this period was determined to be $0.78 to $1.38 per share and we concluded the fair value was $1.10 per share.

During the fourth quarter of 2004, the fair value of our common stock as determined by management increased from $1.10 per share to $4.00. This change in valuation from the third quarter 2004 to the fourth quarter 2004 reflected the operational progress as noted below.

During October 2004, we completed the second private placement of Series C preferred stock units for gross proceeds of $8.1 million at a price of $2.26 per unit (the post reverse split common stock equivalent value was $4.52 per unit). Each unit consisted of one share of Series C preferred stock and one warrant to purchase one share of common stock at an exercise price of $13.00 per share. Since no additional consideration was received for the warrant, the consideration for the preferred stock was less than $2.26 per share. Approximately 35% of the Series C preferred stock units were acquired by new unaffiliated investors. The common stock warrants attached to this issuance were valued at approximately $1.48 per warrant using the Black-Scholes model with a fair value of $4.00 per share of our common stock.

During October 2004, we received a binding Protocol Agreement from the FDA defining the endpoints of the pivotal clinical trial for MelaFind® approval. We believe that the presence of a Protocol Agreement significantly enhances our ability to expedite the FDA approval process. To support our future growth and the commercialization of MelaFind®, our board of directors approved in December 2004, the appointment of key executives. In addition, our board of directors approved the issuance of 75,000 warrants to Allen & Company LLC to purchase common stock with an exercise price of $7.00 per share in exchange for financing advice, acknowledging the need for additional capital to support MelaFind® development. The fair value of the Allen & Company LLC warrant was determined to be $1.60 per warrant using the Black-Scholes method with the following assumptions: common stock value per share $4.00, warrant life of 5 years, a risk-free interest rate of 3.67%, and an expected volatility of 60%. For these reasons, we believe the fair value of our common stock during this period was $4.00 per common share, and accordingly the valuation of options and warrants issued during December 2004 was based upon the $4.00 per share common stock value.

During the first quarter of 2005, we encountered operational issues and management believes these difficulties negatively impacted the fair value of our common stock for this period. Specifically, a study that was initiated in late 2004 under the Protocol Agreement was stopped due to technical difficulties with some of the MelaFind® clinical trial instruments. In addition, we were inspected by the FDA in connection with its DIFOTI® product in March 2005, and we were cited in a FDA Form 483 for failures to comply fully with the FDA's QSR. Since no equity transactions were consummated during this period, we did not determine a new estimated fair value of our common stock during this calendar quarter.

During the second quarter of 2005, progress was made in addressing the issues that we encountered during the first quarter of 2005. With respect to the MelaFind® clinical instruments, we engaged a consultant to direct the MelaFind® product development efforts and oversee the manufacturing process. In addition, we entered into an agreement with ASKION, a precision optics specialty manufacturer, to develop methods for optimizing the design of the MelaFind®

hardware. We provided a report to the FDA outlining our plan to address the technical difficulties with the MelaFind® instruments through a design modification and optimization process with ASKION. On June 30, 2005, we received written confirmation from the FDA that our plan is acceptable. These pre-commercialization instruments will be assembled by ASKION and are expected to be available for the pivotal trial we estimate will commence in early 2006.

We decided to discontinue all operations associated with our DIFOTI® product effective as of April 5, 2005, in order to focus our resources and attention on the development and commercialization of MelaFind®. We are currently seeking an acquirer for the DIFOTI® assets, and we do not expect to have any significant continuing responsibility for the DIFOTI® business after its disposition. In addition, the inspectional findings identified in the FDA Form 483 were discussed in a subsequent meeting with the FDA on April 28, 2005 and did not result in a product recall. We are in the process of addressing the deficiencies noted.

Based on our operational progress during the second quarter of 2005, we determined, in consultation with our underwriters, the fair value of our common stock for our proposed initial public offering to be in the range of $10.00 to $12.00 per share.

In May 2005, we amended stock option agreements for 125,000 shares of our common stock in the aggregate, of three key employees to immediately vest upon the completion of this offering. We will record a charge to operations in the amount of $0.6 million.

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 then current market value of our common stock underlying the options which vest when the milestone is attained. Assuming that all shares offered are sold in this public offering at a price of $5.00 per share, and that upon the attainment of each of the relevant milestones such offering price remains the fair market value per share of our common stock, and that the number of shares of our common stock outstanding after this offering remains 10,513,164, then we will record a compensation expense upon filing our MelaFind® PMA with the FDA of $0.2 million with respect to 50,000 shares of underlying options, and upon our receipt of PMA approval for MelaFind® of $0.2 million with respect to 50,000 shares of underlying options. The employment agreement with Dr. Gulfo includes three separate grants of common stock options. The first two stock option grants for a total of 81,753 shares of our common stock have fully vested. The number of shares of our common stock subject to the third stock option can only be calculated at the time of PMA approval of MelaFind®. The number of shares under this option is equal to that number of shares of our common stock equal to four percent of our fully diluted capital stock at the time of PMA approval of MelaFind® minus the 81,753 options granted to Dr. Gulfo under the employment agreement. Assuming that 10,513,164 shares are outstanding as of the completion of this offering and remain the total number of shares outstanding on the date we receive PMA approval, the number of shares subject to this option would be 387,366. This third stock option grant vests 50% at the time of PMA approval of MelaFind®, and the remaining 50% vest in four equal installments over the one year period following such PMA approval of MelaFind®. We will recognize compensation expense in the amount of $1.8 million over the vesting periods.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service where we have not been invoiced or otherwise notified of the actual cost. This is done as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include:

- professional service fees;
- contract clinical service fees;
- fees paid to contract manufacturers in conjunction with the production of clinical components or materials; and
- fees paid to third party data collection organizations and investigators in conjunction with the clinical trials.

In connection with such service fees, our estimates are most affected by our projections of the timing of services provided relative to the actual level of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under or over estimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often subjective determinations. We make these judgments based upon the facts and circumstances known to us in accordance with accounting principles generally accepted in the US.

Results of Operations (in thousands)

Six Months Ended June 30, 2005 Compared to Six Months Ended June 30, 2004 (Unaudited)

Research and Development Expense. Research and development expense increased by $853 to $1,546 for the six months ended June 30, 2005 from $693 for the six months ended June 30, 2004. Of this increase, $410 was attributable to higher personnel and personnel related costs as we increased headcount to support our research and development programs and $418 relates to increased consulting and outside research fees for the development of our MelaFind® product.

General and Administrative Expense. General and administrative expense increased by $357 to $996 for the six months ended June 30, 2005 from $639 for the six months ended June 30, 2004. The increase is primarily due to higher personnel and personnel related costs of $140 associated with the addition of key management positions, $44 related to rent and moving expenses on the additional office space, share-based compensation expense of $86, and general office related expenses of $79.

Interest (Income)/Expense. Interest (income)/ expense for the six months ended June 30, 2005 was ($63) compared to $82 for the corresponding period in 2004. The increase in income for the six months ended June 30, 2005 was due to the higher average cash, cash equivalents and marketable securities balance compared to the prior year period. The interest expense for the six months ended June 30, 2004 principally relates to an imputed interest charge of $80 in connection with financings from related parties.

Year Ended December 31, 2004 Compared to Year Ended December 31, 2003

Research and Development Expense. Research and development expenses increased by $1,064, from $828 for the year ended December 31, 2003 to $1,892 for the year ended December 31, 2004. This increase relates to increased headcount to support our research and development programs in the amount of $715, and $332 represents increased consulting and outside research fees related to the development of MelaFind®. For the year ended December 31, 2004 research and development costs were approximately 60% of total operating expenses. Clinical and regulatory expense, a component of research and development expense totaled approximately $797 for the year ended December 31, 2004. We expect our research and development expenses to increase in connection with our clinical trials and other development activities as we advance our MelaFind® pivotal study and complete the PMA regulatory approval process.

General and Administrative Expense. General and administrative expenses increased by $200, to $1,234 for the year ended December 31, 2004 from $1,034 for the year ended December 31, 2003. The increase was principally attributable to $150 in stock-based compensation to non-employee board members, an increase in personnel costs of $63, MelaFind® reimbursement and pre-marketing costs of $69, offset in part by lower consulting fees of $82. For the year ended December 31, 2004, general and administrative expenses were approximately 40% of total operating expenses. We expect that our general and administrative expenses will increase to support the additional costs associated with being a public company.

Interest (Income)/ Expense. Interest (income)/ expense for the year ended December 31, 2004 was $67 compared to $76 for the corresponding period in 2003. The decrease was due principally to higher interest income in 2004 associated with a higher average cash, cash equivalents and marketable securities balance compared to the prior year.

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Revenue. Grant revenue generated in 2002 in the amount of $547 represents federal grants received in conjunction with an undertaking to perform certain research.

Cost of Grant Revenue. The cost of grant revenue for the year ended December 31, 2002 represents the expenses attributable to the grant revenue and consists primarily of payroll and related costs amounting to $564.

Research and Development Expense. Research and development expenses increased $424 to $828 for the year ended December 31, 2003 from $404 for the year ended December 31, 2002. This increase was principally attributable to personnel and personnel related costs that specifically supported the grant program in 2002, and were classified as cost of grant revenue in 2002 and $93 related to an increase in other consulting and outside research fees supporting the development of our MelaFind® product. For the year ended December 31, 2003 research and development costs were approximately 45% of total operating expenses. Clinical and regulatory expense, a component of research and development expense totaled approximately $50 for the year ended December 31, 2003.

General and Administrative Expense. General and administrative expenses increased by $523 to $1034 for the year ended December 31, 2003 from $511 for the year ended December 31, 2002. The increase was principally attributable to personnel and personnel related costs of $488 and an increase in consulting fees of $35. For the year ended December 31, 2003 general and administrative expenses were approximately 55% of total operating expenses.

Interest (Income)/ Expense. Interest (income)/ expense for the year ended December 31, 2003 was $76 compared to $8 for the corresponding period in 2002. The increase was due to a charge of $45 associated with the value of the beneficial conversion feature for a promissory note during 2003.

Liquidity and Capital Resources (in thousands)

From inception, we have financed our operations primarily through the use of working capital from private placements of equity securities and by applying for and obtaining a series of National Institute of Health Small Business Innovative Research grants and similar grants. To date, we have not borrowed (other than by issuing convertible notes, all of which have been converted into equity) or financed our operations through significant equipment leases, financing loans or other debt instruments. As of June 30, 2005, we had $3,794 in cash, cash equivalents and marketable securities as compared to $6,703 at December 31, 2004. Our cash, cash equivalents and marketable securities are liquid investments with a maturity within one year and consist of investments in money market funds with a commercial bank and short-term US Treasury obligations and federal agency notes.

Cash Flows from Operating Activities. Net cash used in operations was $2,890 for the six months ended June 30, 2005. For the years ended December 31, 2002, 2003 and 2004 the net cash used in operations was $684, $1,699, and $3,065 respectively. For all periods, cash used in operations was attributable primarily to net losses after adjustment for non-cash charges related to depreciation and other changes in operating assets and liabilities.

Cash from Investing Activities. Net cash provided by our investing activities was $2,923 for the six months ended June 30, 2005 principally relating to the redemption of investments. For the years ended December 31, 2002, 2003 and 2004 the net cash provided by (used in) investing activities was $518, $(8) and $(6,677) respectively. The increase in cash used in investing activities in the years ended December 31, 2003 and 2004 was principally related to the net purchase of investments and equipment from the proceeds of our private placement financings. Cash used in investing activities for the year ended December 31, 2002 reflected the redemption of investments.

Cash Flows from Financing Activities. Net cash provided by financing activities was $35 for the six months ended June 30, 2005. For the years ended December 31, 2002, 2003 and 2004 the net cash flows provided by financing activities was zero, $1,816 and $9,733 respectively. For these periods, financing cash flows reflected the proceeds from the issuance of common stock, and preferred stock.

We face certain risks and uncertainties, which are present in many emerging medical device companies. At June 30, 2005, we had an accumulated deficit of $16,716 and anticipate that we will continue to incur net losses for the foreseeable future in the development and commercialization of the Melafind® device. If this offering is not

consummated, we would need to limit the level of discretionary expenditures or pursue alternate sources of funding to sustain the continued development of the MelaFind® device at the same level.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized our principal product, MelaFind®. We anticipate that we will continue to incur net losses for the foreseeable future as we continue to develop the MelaFind® system, expand our clinical development team and corporate infrastructure, and prepare for the potential commercial launch of MelaFind®. We do not expect to generate significant product revenue until we successfully obtain PMA approval for and begin selling MelaFind®. In order to achieve significant commercialization of MelaFind® we will need to obtain additional funding. We believe that the net proceeds from this offering, together with our current cash, cash equivalents and marketable securities and interest we earn on these balances, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through mid 2007. If existing cash and cash generated from this offering are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain a credit facility. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of, delay or eliminate some or all of planned product research development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the development of medical devices such as MelaFind®, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including, but not limited to:

- the schedule, costs, and results of our clinical trials;
- the success of our research and development efforts;
- 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 payors, or the amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind®;
- the cost of commercialization activities, including 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.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2004 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

Payments Due by Period

Contractual Obligations	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
			(dollars in thousands)		
Operating Leases	$ 1,114	$ 205	$ 634	$ 275	—
Total	$ 1,114	$ 205	$ 634	$ 275	—

Our long-term obligations are two non-cancelable operating leases for space expiring June 2009 and November 2010. The lease on 3,700 square feet of office, laboratory and assembly space expires in June 2009 and the lease on 2,800 square feet of office space expires November 2010.

Related Party Transactions

For a description of our related party transactions, see the "Related party transactions" section of this prospectus and the related notes to our financial statements appearing at the end of this prospectus.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is confined to our cash equivalents and short-term investments. We invest in high-quality financial instruments; primarily money market funds, federal agency notes, and US Treasury obligations, with the effective duration of the portfolio within one year which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

Recent Accounting Pronouncements

In May 2003, FASB issued Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS No. 150). This statement establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatorily redeemable financial instruments of nonpublic companies. FASB has indefinitely deferred implementation of some provisions of SFAS No. 150. The adoption of SFAS No. 150 did not have a material effect on our financial position or results of operations.

Business

Overview

We are a medical device company focused on the design and development 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 multiple wavelengths of light to capture images of suspicious pigmented skin lesions and extract data. The data are then analyzed against our proprietary database of melanomas and benign lesions using our sophisticated algorithms in order to provide information to the physician and produce a recommendation of whether the lesion should be biopsied.

The components of the MelaFind® system include:

- a *hand-held imaging device*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- our *proprietary database* of pigmented skin lesions, which we believe to be the largest in the US;
- our *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions; and
- a *central server* in our offices that is intended to perform quality control functions and provide reports to the physician and in commercial use, will be connected to physicians' offices via the internet.

We have entered into a binding Protocol Agreement with the FDA which is an agreement for the conduct of the pivotal trial in order to establish the safety and effectiveness of MelaFind®. We believe the presence of the Protocol Agreement significantly enhances our ability to expedite the FDA approval process. We stopped a study that was initiated in late 2004 under the Protocol Agreement due to technical difficulties with some of the MelaFind® clinical trial instruments. The FDA has provided confirmation that our plan to correct the technical issues and start a new pivotal trial to satisfy the Protocol Agreement is acceptable. Management estimates that the pivotal trial will commence in early 2006 at over 20 US clinical study sites, and anticipates PMA approval to commercialize MelaFind® in 2007.

To date, we have not generated any revenues from MelaFind®. All of our historical revenues have come from activities and products that have since been discontinued, including our DIFOTI® product, a non-invasive imaging device for the detection of dental cavities. We decided to discontinue all operations associated with our DIFOTI® product, effective as of April 5, 2005, in order to focus our resources on the development and commercialization of MelaFind®.

Cancers of the skin have a higher incidence than all other cancers combined, and the rates are rising dramatically. In 2005, over 120,000 new cases of melanoma are projected. Melanoma is responsible for approximately 80% of skin cancer fatalities and is the deadliest of all skin cancers as there is currently no cure for advanced stage melanoma. However, early detection of skin cancers like melanoma can lead to virtually a 100% cure rate. Advanced stage melanoma is costly to treat and is responsible for approximately 90% of the total spending on melanoma treatment in the US, costing up to $170,000 per patient. If diagnosed early, however, melanoma is almost always cured by simple resection at a cost of approximately $1,800 per patient.

Because early detection is critical to survival, the American Cancer Society recommends that individuals age 40 years and older have complete skin examinations on an annual basis. According to the 2000 US Census data, over 100 million Americans in the US are over age 40. Furthermore, there are more than 20 million individuals in the US who have dysplastic nevi, a type of pigmented skin lesion that when present is associated with an increased risk of melanoma. These individuals warrant more frequent observation.

Melanomas are mainly diagnosed by dermatologists and/or primary care physicians using visual clinical evaluation. Physicians assess pigmented skin lesions using the "ABCDE" criteria, Asymmetry, Border irregularity, Color variation, Diameter greater than 6 mm, and Evolving — change in ABCD over time. This assessment is subjective and results in missed melanomas, as well as a ratio of benign lesions biopsied to melanomas confirmed that is highly variable and as high as 40 to 1 for dermatologists and as high as 50 to 1 for primary care physicians.

To date, MelaFind® has been studied on over 5,000 skin lesions from over 3,500 patients at over 20 clinics. Our clinical studies have demonstrated that MelaFind® missed fewer melanomas and produced fewer false positives than experienced by study dermatologists, who are skin cancer specialists. The performance of a diagnostic is measured in terms of *"sensitivity"* (the ability to detect disease when disease is present) and *"specificity"* (the ability to exclude disease when disease is not present). In the largest blinded trial that we have performed to date on 352 suspicious pigmented skin lesions, using our most advanced system, MelaFind® did not miss a melanoma (measured sensitivity of 100%) and achieved 48.4% specificity compared to the study dermatologists' sensitivity of 96.4% and specificity of 28.4%.

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

Our objective is for MelaFind® to become an integral part of the standard of care in melanoma detection.

The Market Opportunity

Cancer of the skin (nonmelanoma and melanoma skin cancers combined) is the most common of all cancers, projected to be over 1.3 million cases in 2005 and estimated to account for more than 50% of all cancers. In 2005, over 120,000 new cases of melanoma are projected. There are three significant forms of skin cancer: basal cell, accounting for approximately 75% of skin cancer; squamous cell, totaling approximately 20%; and melanoma, which accounts for an estimated 4% of skin cancer cases, but is responsible for approximately 80% of all deaths from skin cancer. The American Cancer Society projects 10,600 deaths from skin cancer in 2005 — 7,800 from melanoma and 2,800 from other skin cancers. Since 1973, the mortality rate for melanoma has increased by 50%. Since approximately 62% of melanomas and 45% of melanoma deaths occur prior to age 65, melanoma places significant burdens on the healthcare system well beyond Medicare.

Melanoma, if left untreated, can be fatal. If diagnosed and removed early in its evolution, when confined to the outermost skin layer and deemed to be "in situ," it is virtually 100% curable. Invasive melanomas that are thin and extend into the uppermost regions of the second skin layer still have excellent cure rates (greater than 90%). However, once the cancer advances into the deeper layers of skin, the risk of metastasis (spreading to other parts of the body) increases. Metastases can occur when the tumor enters into lymphatic channels and newly formed blood vessels, potentially resulting in significant morbidity (illness) and mortality (death). Once the cancer has advanced and metastasized to other parts of the body, it is difficult to treat. At this advanced stage, the five year survival rate is reported to be only 10%. Moreover, survival prospects for those with advanced melanoma have not improved over the past three decades.

Melanoma is currently the subject of significant attention in the medical community. In part, this attention is due to the fact that it is the fastest growing cancer. It is also the most common cancer in young adults ages 20-30, and currently there are more new cases of melanoma than HIV/ AIDS. In women ages 25-30, melanoma is the primary cause of cancer death. In women ages 30-35, melanoma is the second leading cause of death after breast cancer. Recent published papers identify a strong correlation between breast cancer and melanoma.

Because early detection is critical to survival, the American Cancer Society recommends that individuals 40 years and older have complete skin examinations on an annual basis. The 2000 US Census indicates that there are over 100 million Americans over the age of 40 in the US. Furthermore, there are more than 20 million individuals in the US who have dysplastic nevi, a type of pigmented skin lesion that when present is associated with an increased risk of melanoma. Such individuals warrant more frequent observation.

Our Strategy

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

- **Pursue the timely FDA approval of MelaFind®.** We have entered into a binding Protocol Agreement with the FDA for the conduct of the pivotal trial of MelaFind®. Management estimates that the study will commence in early 2006 at over 20 US clinical study sites, and anticipates PMA approval to commercialize MelaFind® in 2007.
- **Establish MelaFind® as the leading technology for assisting in the detection of melanoma.** We have invested considerable capital and expertise into developing our core technology platform, which is protected by six US patents. We will continue to refine and optimize this technology to ensure that MelaFind® is the leading system for assisting in the detection of melanoma.
- **Obtain third party payor reimbursement to support our recurring revenue pricing model.** We intend to offer MelaFind® on a per patient basis, creating a recurring revenue stream. To do so, we will seek to obtain third party reimbursement as well as private pay alternatives. We are working with experts to create an evidence-based medicine evaluation model consistent with those used to support positive coverage decisions by CMS and private payors for similar products. The value drivers in the model include the cost savings associated with early detection (approximately $168,000 per patient) and fewer biopsies. We believe that the use of MelaFind® could result in substantial savings to the US healthcare system.
- **Commercialize MelaFind® using multiple sales and marketing strategies.** Our internal sales and marketing effort will focus initially on “high volume/key opinion leader” dermatologists with specialties in the diagnosis and treatment of melanoma. To enter the larger US markets of general dermatologists, plastic surgeons, and primary care physicians, and for international markets, we intend to establish partnerships with pharmaceutical and/or diagnostic device companies with an established presence in these markets. While we believe obtaining a positive coverage decision from CMS may take an additional 18 to 36 months following PMA approval, and obtaining a positive coverage decision from private payors, managed care organizations and state Medicare administrative contractors may take at least 6 to 12 months following PMA approval, we intend to commence sales of MelaFind® immediately upon receiving PMA approval for physicians to offer MelaFind® to their patients on a self-pay basis.

Limitations of Current Melanoma Diagnosis

The current primary method for detecting melanoma is based on physicians’ ability to recognize patterns using the naked eye; this is known as clinical examination. Physicians assess pigmented skin lesions using the “ABCDE” criteria, Asymmetry, Border irregularity, Color variation, Diameter greater than 6 mm, and Evolving — change in ABCD over time. This subjective interpretation relies on physician experience and skill. The ratio of benign lesions biopsied to melanomas confirmed can be variable, ranging as high as 40 to 1 for dermatologists and as high as 50 to 1 for primary care physicians. In contrast, MelaFind® delivers an objective assessment based on numerical scores assigned to the suspicious skin lesion under evaluation. Further, clinical examination is limited to the surface appearance of the suspicious pigmented skin lesion, whereas MelaFind® utilizes information derived from up to 2.5 mm deep into the skin.

Dermatologists who specialize in the management of pigmented skin lesions may also use dermoscopy, a method of viewing lesions under magnification. Although dermoscopy provides more information than unaided visual examination, mastery of the technique necessitates many years of training and experience. Proper use of dermoscopy can reduce the number of unnecessary biopsies of benign lesions, but even dermoscopy experts biopsy 3-10 benign lesions for every melanoma detected.

Most dermatologists generally use only visual clinical evaluation for melanoma detection. Consequently, they biopsy up to 40 benign lesions for every melanoma detected. While many primary care physicians immediately refer patients with suspicious pigmented skin lesions to a specialist, an increasing number perform biopsies on skin lesions themselves. Their lack of specialist training in identifying suspect lesions makes their diagnostic accuracy much lower in terms of

both sensitivity and specificity. This results in 40% misdiagnosed melanomas and a ratio of benign lesions biopsied to melanomas confirmed of up to 50 to 1.

MelaFind® Product Description

MelaFind® is a non-invasive system for assisting in the early detection of melanoma. The MelaFind® system is comprised of a point-of-care, hand-held imaging device that, in commercial use, is intended to be connected via the internet to a central server in our offices. MelaFind® employs multiple wavelengths of light to obtain data from images of suspicious lesions; the data are analyzed against our proprietary database of melanomas and benign lesions using our sophisticated algorithms. When marketed, a report will be transmitted to the physician's office containing MelaFind®'s recommendation of whether the lesion should be biopsied. The key components of the MelaFind® system are listed below:

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

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

Our proprietary database of pigmented skin lesions, which includes in vivo MelaFind® images and corresponding histological results of over 5,000 biopsied lesions from over 3,500 patients, which we believe to be the largest such database in the US and a substantial barrier to competition.

Our lesion classifiers, which are sophisticated mathematical algorithms that analyze the MelaFind® images and extract lesion feature information from the images; the features are used to classify the lesions as either suspicious for melanoma or not suspicious for melanoma.

A central server located in our offices, which is intended to perform quality control functions and provide diagnostic reports to the physician.

The "brain" of the MelaFind® system, the *Lesion Classifier,* distinguishes melanoma from non-melanoma using the lesion features extracted and measured by the hand-held imaging device. The *Lesion Classifiers* are developed from our proprietary database of pigmented skin lesions and sophisticated mathematical algorithms. The mathematical formulas and algorithms used by the *Lesion Classifiers* are devised and optimized through the process of "classifier training" using lesions from our proprietary database. *Lesion Classifier* development and training is an iterative process involving: (1) selection of the lesion features that provide for optimal lesion discrimination; (2) optimization of the mathematical formulas to differentiate benign lesions from melanoma; and (3) expansion of the size and diversity of our proprietary lesion database. The performance of the *Lesion Classifiers* is directly related to the size of the database used in classifier training, as well as the degree to which the training database is representative of the lesions that will be evaluated by MelaFind® in commercial use.

As with many diagnostic systems, the diagnostic performance of MelaFind® is characterized using two measures: (1) ***sensitivity*** — the ability to detect disease when it is present; and (2) ***specificity*** — the ability to exclude disease when it is not present. Since sensitivity and specificity are typically trade-offs, meaning that as one parameter increases the other decreases, the MelaFind® *Lesion Classifier* is developed and trained with the intention that MelaFind® will detect all melanomas in the training data set with the highest possible specificity.

Reliable functioning of the MelaFind® system is critical to its utility and success in the marketplace. Automated self-calibration tests are performed by the hand-held device to ensure proper functionality. When marketed, the central server will also perform tests on the hand-held device to determine whether its functioning is within appropriate limits, that is, that the quantitative data on lesion and calibration image features provided by MelaFind® are within a pre-determined expected range of values. The server will not permit MelaFind® to provide diagnostic information unless the hand-held device is functioning properly.

MelaFind® Regulatory Status

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

The primary endpoints of the study include: (1) greater than 95% (lower confidence bound (a statistically derived lower limit of a measured or observed value based on the number of observations used to derive the measured or observed value)) sensitivity for detection of melanoma (99% observed sensitivity); and (2) statistically significant greater specificity in ruling out melanoma when compared to study dermatologists. The lower confidence bound of 95% sensitivity is a statistically-derived lower limit of sensitivity based on an observed sensitivity of 99%. This means that in order to satisfy the sensitivity requirement, MelaFind® must correctly identify at least 92 of the 93 melanomas, that is, miss either none or one melanoma in the pivotal trial. In order to satisfy the specificity requirement, MelaFind® must demonstrate a higher specificity than study dermatologists at a level where the probability of obtaining such a result by chance is less than 5%. For illustrative purposes, assuming a specificity of 25% for study dermatologists, the specificity of MelaFind® would need to be at least 32% in order for the difference to be statistically significant at the 95% confidence level.

We initiated a clinical trial under the terms of the Protocol Agreement at the end of 2004. However, technical operational issues with the systems were experienced, requiring further refinement. We are continuing this study as a supportive pilot study. A pilot study is one that provides information regarding the operation of a device in the clinical setting as well as the feasibility of various clinical trial evaluations. Pilot studies are often used to help refine certain elements of a planned pivotal trial and serve to train study personnel in advance of a pivotal trial.

We are currently refining the hardware systems and expect to have new systems available in order to start the pivotal trial in early 2006. The pivotal trial for PMA approval of MelaFind® will be conducted under the terms of the Protocol Agreement. We have reviewed our strategy with the FDA and have obtained confirmation from the FDA that our plan to correct the technical issues by refining the hardware systems and to start a new pivotal trial to satisfy the Protocol Agreement is acceptable.

For commercialization outside the US, approvals from appropriate regulatory bodies within other countries will be required. Once PMA approval is obtained, we may proceed with applications to commercialize in various countries pending further assessment of market opportunities and the possible identification of strategic partners.

Clinical Studies of MelaFind®

Goals and Objectives

MelaFind® has been studied on over 5,000 skin lesions from over 3,500 patients during the past five years at over 20 clinical sites in the US, as well as two sites in Europe and one in Australia. We aim to develop a system with a sensitivity of at least 95% in detecting melanoma. Our goals are to complete pre-commercialization design and testing of the hand-held imaging device and its associated software, as well as to establish a database of approximately 300 melanomas, including *in vivo* MelaFind® images and biopsy results, for MelaFind® *Lesion Classifier* algorithm development and training. Statistically, in order to have a high level of confidence of success, we set the lower confidence bound at 99%, which requires approximately 300 melanomas in the classifier training database. To date, the MelaFind® lesion database includes approximately 268 melanomas.

We are developing in parallel several MelaFind® *Lesion Classifiers*, which differ in the algorithms, as well as in the specific lesion features and relative weights used in the mathematical formulas. Prior to conducting the analysis of the data from the pivotal trial under the Protocol Agreement, the optimal *Lesion Classifier* will be selected. The primary means by which the performance of the MelaFind® *Lesion Classifiers* is evaluated is through measures of ***sensitivity*** (the ability to detect disease when present) and ***specificity*** (the ability to exclude disease when not present).

The reference standard used for comparison of the results of MelaFind® and study dermatologists is histological analysis of the biopsied lesions by a group of expert pathologists. MelaFind® images of pigmented skin lesions (melanomas and non-melanomas) and the histological results of the corresponding biopsied lesions comprise our training database of lesions. When the *Lesion Classifiers* are tested on the database used in training, this is called a "training study." When the *Lesion Classifiers* are tested on a set of lesions not used in training, this is called a "blinded test," which is a simulation of anticipated real-life prospective classifier performance.

Our ultimate goal for MelaFind® is to demonstrate sensitivity of at least 95%, and superior specificity as compared to study dermatologists in the pivotal blinded test for PMA approval.

MelaFind® Development History — Hardware and Software

In developing the MelaFind® system we have tested both a first and second generation hand-held imaging device, and are in the process of developing a pre-commercialization version for use in our pivotal clinical trial. Our research, development and clinical testing efforts have been designed to improve our MelaFind® technology platform, including the imaging device and lesion classifiers, and to enhance our lesion database.

We began using first generation hand-held imaging devices in clinical studies in 2001. In 2002, we expanded the clinical research program to additional study sites equipped with second generation hand-held imaging devices. The aim of the study, which is ongoing, is to build the MelaFind® proprietary lesion database for use in *Lesion Classifier* training. The study calls for the MelaFind® hand-held imaging device to acquire images of pigmented skin lesions scheduled for biopsy. After biopsy, the histological slides are collected and sent for central histological review by a panel of experts.

The results of initial training studies and blinded tests were not to the expected level of performance. We determined the cause to be a flaw in the second generation hand-held imaging devices, which were subsequently shown to exhibit highly variable levels of stray light, an optical artifact. Therefore, we ceased producing this generation of hand-held imaging devices and purged the training database of lesion images acquired with them. We also incorporated a manufacturing specification for stray light which, prior to this time, was not included. Subsequent training studies and blinded tests performed using only first generation hand-held imaging devices confirmed our earlier favorable results: MelaFind® missed none or very few melanomas, and was shown to have higher specificity than study dermatologists, as shown in the tables below. See "Business — Clinical Studies of MelaFind® — Results of Training Studies and Blinded Tests."

We initiated a clinical study under the terms of the Protocol Agreement with the FDA in late 2004 using first generation hand-held imaging devices. However, several technical operating issues with these older systems were experienced, requiring further refinement. Third generation hand-held imaging devices were produced in 2004 and early 2005. These serve as the basis of the design that is currently being used to generate final, pre-commercialization hand-held imaging devices, which will be utilized in the pivotal study for PMA approval under the terms of the Protocol Agreement.

Along with hardware development efforts, we have also developed, tested, and continue to refine the software components of the system, including lesion filters, calibration algorithms, lesion classification algorithms, and hardware normalization software. We plan to finalize these key elements of the software prior to the analysis of the data obtained from the pivotal trial for PMA approval.

Results of Training Studies and Blinded Tests

The first iteration of MelaFind® *Lesion Classifiers*, *Lesion Classifiers A-1 and B*, employed a single-step process, that is, an algorithm that differentiates melanoma from all other pigmented skin lesions. These MelaFind® classifiers were trained on a total of 1,129 lesions — 109 melanomas, 70 high grade dysplastic nevi, and 950 other pigmented skin lesions. For the blinded test, a different group of 477 pigmented skin lesions, including 26 melanomas, 11 high grade dysplastic nevi, and 440 other lesions were included. None of these lesions were used in classifier training. The results

of the training study and blinded tests for MelaFind® *Lesion Classifiers A-1* and *B*, as well as study dermatologists, are summarized below.

August 2003 — Training Study and Blinded Test Results

	Training study		Blinded test	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
MelaFind® *Lesion Classifier A-1*	100%	45.6%	80.8%	44.3%
MelaFind® *Lesion Classifier B*	96.3%	21.9%	80.8%	25.5%
Study Dermatologists	N/A	N/A	96.2%	17.3%

The performance of the MelaFind® *Lesion Classifiers* on the blinded data set was significantly below results from the training study. The first attempt to improve the performance was by developing a new MelaFind® *Lesion Classifier A*, employing a three-step process *(A-3)*, which was accomplished in November 2003. A three-step process employs algorithms that differentiate melanoma from three other classes of pigmented skin lesions. The new classifier was re-trained on the original data set of lesions (109 melanomas, 70 high grade dysplastic nevi, and 950 other pigmented skin lesions), tested on the training set and then tested on the same blinded data set used in August 2003 (26 melanomas, 11 high grade dysplastic nevi, and 440 other lesions). The following table summarizes the results of the tests on the training and blinded data sets. Note that MelaFind® *Lesion Classifier B*, which accommodates a single-step process only, was not evaluated in these exercises.

November 2003 — Training Study and Blinded Test Results

	Training study		Blinded test	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
MelaFind® *Lesion Classifier A-3*	100%	28.5%	100%	25.7%
Study Dermatologists	N/A	N/A	96.2%	17.3%

Review of the data indicated that the three-step MelaFind® *Lesion Classifier A-3*, which was trained with lesions acquired from first and second generation MelaFind® hand-held imaging devices, was much less specific on the training database (28.5%) than the single-step classifier MelaFind® *Lesion Classifier A-1*, which was trained on lesions acquired using only first generation hand-held imaging devices (45.6%). A complete analysis of all MelaFind® devices from the clinical sites indicated a systematic difference between the first generation and second generation MelaFind® hand-held imaging devices. The second generation hand-held imaging devices exhibited a significantly greater amount of stray light than the first generation hand-held imaging devices. Stray light induces variable imaging artifacts that cannot be predicted or accounted for in the software algorithms, and introduces higher probability for error. Therefore, in February 2004, all lesions acquired using second generation hand-held imaging devices were removed from the training and testing databases. The three-step MelaFind® *Lesion Classifier A-3* was then trained on a set of lesions acquired solely from first generation hand-held imaging devices including 113 melanomas, 69 high grade dysplastic nevi, and 987 other pigmented skin lesions. A blinded test was conducted on 262 lesions (21 melanoma, 8 high grade dysplastic nevi, and 233 other lesions) not used in classifier training and acquired using first generation hand-held imaging devices only. The following table summarizes the results.

February 2004 — Results of Training Study and Blinded Test after Removing Lesions Obtained from Second Generation Hand-Held Imaging Devices

	Training study		Blinded test	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
MelaFind® *Lesion Classifier A-3*	100%	43.8%	100%	44.2%
Study Dermatologists	N/A	N/A	95.0%	28.3%

These results demonstrated the importance of minimizing stray light and establishing a product specification for stray light. This specification was instituted in our assembly process following this analysis. As part of the continued development, a four-step MelaFind® *Lesion Classifier A-4* was introduced in March 2004. A four-step process employs algorithms that differentiate melanoma from four other classes of pigmented skin lesions. This classifier performed better compared with the three-step classifier, as summarized in the following table.

March 2004 — MelaFind® Lesion Classifiers: Three-step vs. Four-step Training Study and Blinded Test Results

	Training study		Blinded test	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
MelaFind® *Lesion Classifier A-3*	100%	43.8%	100%	44.2%
MelaFind® *Lesion Classifier A-4*	100%	48.9%	100%	48.1%
Study Dermatologists	N/A	N/A	95.0%	28.3%

Due to the enhanced specificity of the four-step classifier *A-4* compared to the three-step classifier *A-3*, as seen in the preceding table, the four-step classifier was selected for further development and testing. In May 2004, the largest blinded test was performed on a separate set of 352 lesions (including 28 melanomas, 14 high grade dysplastic nevi, and 310 other pigmented skin lesions) that were not used in classifier training. The results of sensitivity and specificity of MelaFind® *Lesion Classifiers A-4 and B* and study dermatologists are summarized in the following table.

May 2004 — Training Study and Blinded Test Results

	Training study		Blinded test	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
MelaFind® *Lesion Classifier A-4*	100%	53.2%	100%	48.4%
MelaFind® *Lesion Classifier B*	100%	38.0%	96.4%	32.9%
Study Dermatologists	N/A	N/A	96.4%	28.4%

In January 2005, with no additional classifier training and in an effort to rigorously test the limits of the MelaFind® *Lesion Classifiers*, another blinded test was performed on 228 new lesions (28 melanomas, 4 high grade dysplastic nevi, and 196 other pigmented skin lesions). The lesions in this blinded test were acquired from the first generation MelaFind® hand-held imaging devices that had been at the clinical sites for a longer period of time than in any blinded test to date. *Lesion Classifier* training was not performed using MelaFind® hand-held imaging devices that had been at the clinical sites for longer periods of time. A new four-step MelaFind® *Lesion Classifier C-4* with a revised step was also evaluated in the blinded test. The results are summarized in the following table.

January 2005 — Second Blinded Test Results using March 2004 Classifiers

	Sensitivity	**Specificity**
MelaFind® *Lesion Classifier A-4*	82.1%	37.2%
MelaFind® *Lesion Classifier B*	96.4%	21.0%
MelaFind® *Lesion Classifier C-4*	92.9%	35.7%
Study Dermatologists	92.9%	23.0%

In evaluating the MelaFind® hand-held imaging devices used in the January 2005 blinded test, we found that several MelaFind® devices were not performing within specifications. Certain lesions had some feature measurements significantly outside of the range of the previous data. This led to the identification of specific problems with the hardware, which enabled a new and more robust design of MelaFind® hand-held imaging devices. Had these devices

performed within specifications, we believe that the sensitivity of MelaFind® *Lesion Classifiers A-4 and C-4* would have been 96.4%, that is, they would have missed one melanoma, compared to study dermatologists who missed two melanomas.

We are utilizing the findings of the blinded tests to refine the design of hardware to further develop the lesion classification algorithms, to expand the training database, and to develop improved calibration methods to ensure appropriate functioning of each hand-held imaging device. As demonstrated in the January 2005 blinded test, melanomas can be missed when MelaFind® systems that do not meet specifications are used to acquire images, and when melanoma lesion types (for instance, nodular melanomas, a melanoma type that is often missed by dermatologists in early stages) are not adequately represented in the training database. In order to address these situations, we have: (1) incorporated a weekly field calibration test to evaluate system performance in order to identify and disable MelaFind® systems that are not functioning within specifications; (2) intensified our effort to obtain images of nodular melanomas for inclusion in the targeted 300 melanoma database for the final *Lesion Classifier*; and (3) refined our algorithms to result in either a positive reading of melanoma when MelaFind® images reveal characteristics well outside the ranges of lesions in the final training database, or to report that MelaFind® cannot provide a diagnosis in this circumstance. As mentioned above, had these devices performed within specifications, we believe that the sensitivity of MelaFind® *Lesion Classifiers A-4 and C-4* would have been 96.4%, that is, they would have missed one melanoma, compared to study dermatologists who missed two melanomas.

Conclusion

In the largest clinical study performed to date on 352 pigmented skin lesions, MelaFind® identified all melanomas (100% measured sensitivity) and had a specificity superior to study dermatologists on a statistically significant basis (48.4% versus 28.4%; the probability of obtaining this result by chance was less than 0.0001). Taken together, we believe the clinical studies performed to date demonstrate that MelaFind® hardware systems that are functioning within specifications and that use the most advanced MelaFind® software and classifiers, provide results consistent with the requirements of the Protocol Agreement, that is, specificity that is superior to study dermatologists on a statistically significant basis, and observed sensitivity of at least 99%.

The studies performed to date have been executed with prototype hardware systems as well as MelaFind® classifiers and software that were under development. We believe that results similar or superior to the results obtained in the largest study will be observed in the pivotal clinical study for PMA approval, which will employ pre-commercialization hardware systems with the most advanced software and MelaFind® classifiers. We believe that the pivotal study will demonstrate specificity superior to study dermatologists on a statistically significant basis and satisfy the requirements of the Protocol Agreement.

Sales and Marketing

We plan to offer MelaFind® as a point-of-care online service. This approach is intended to provide us with the advantage of recurring revenues corresponding to the number of patients examined and to provide the physician with access to our technology without having to make a significant capital investment.

Our sales and marketing strategy is to initially establish focused sales, marketing, and distribution organization in North America. We plan to focus our commercialization efforts initially on “high volume/key opinion leader” dermatologists who are strongly focused on the diagnosis and treatment of melanoma. For the expansion to the larger US markets of general dermatologists, plastic surgeons, and primary care physicians, and for international markets, we intend to establish development and commercialization partnerships with pharmaceutical and/or diagnostic device companies with an established competency in the market to accelerate the product introduction and to maximize the breadth of the commercial opportunity. At this time, we have not yet established any commercialization partnerships.

We believe that the ultimate market for MelaFind® is in the primary care setting. When used by primary care physicians, MelaFind® could have a significant public health benefit and a favorable impact on healthcare costs. Primary care physicians are at the front line of early detection, but their lack of specialist training in identifying suspect lesions makes

the achievement of a high level of diagnostic accuracy challenging. We believe that MelaFind® can significantly assist primary care physicians in improving their diagnostic acumen.

The MelaFind® Value Proposition for the Healthcare System

We are currently working with experts on a quantitative analysis of the value proposition of the use of MelaFind® by both dermatologists and primary care physicians using Evidence-Based Medicine evaluation techniques. This strategy is consistent with the approach that has been used to support positive coverage decisions by CMS and private payors for other products. The value drivers include: (1) the diagnosis of melanoma at the early curable stages, as opposed to advanced stages, allowing for both a greater opportunity to cure and a reduction in treatment costs by approximately 99%; and (2) reduced number of referrals for evaluation and biopsy of benign pigmented skin lesions. We believe that the use of MelaFind® could result in substantial savings to the US healthcare system.

Our Reimbursement Strategy

We are aware of no Current Procedural Terminology (CPT) code that is specifically applicable to the use of MelaFind®. Therefore, we have engaged the services of expert consultants with extensive experience in the CPT and coverage decision processes to assist us in the submission of appropriate applications to obtain a CPT code(s) and positive coverage decisions from CMS and private payors.

In advance of obtaining a CPT code, we intend to extend our efforts to secure coverage by private payors and Medicare administrative contractors. Securing coverage first through private payors and Medicare administrative contractors is a common strategy for facilitating national Medicare coverage. Our efforts to secure reimbursement for services using MelaFind® will focus first on private payors and Medicare administrative contractors, particularly in sunbelt locations and in areas that have been shown to be underserved by dermatologists.

In the US, healthcare providers that utilize medical systems such as MelaFind®, generally rely on third-party payors, including Medicare, Medicaid, private health insurance carriers, and managed care organizations, to reimburse part, but not necessarily all, of the costs and fees associated with the procedures performed using these devices. Public and professional concern about the cost of medical care and new technologies has evoked a variety of remedies. Third-party payors are increasingly challenging the pricing of medical products and procedures. Guidelines have been established that recognize the need for clinical strategies to assess the cost-effectiveness of new diagnostic tools or procedures (Evidence-Based Medicine), in the hope of reducing the variations in diagnostic and treatment protocols and reducing healthcare expenditures.

Insurers are also attempting to curb utilization by applying a rational analysis of the costs versus benefits of new technologies.

The Evidence-Based Medicine evaluation that we are undertaking is central to our efforts to obtain positive coverage decisions from CMS and private insurers. The importance of Evidence-Based Medicine is underscored by recent actions by CMS, including its proposed Covered with Evidence Development initiative designed to provide quicker access to new technologies for beneficiaries while assuring that appropriate evidence for final coverage decisions will be obtained.

Assuming FDA approval of MelaFind® in 2007, we anticipate submitting an application for a new CPT code to the American Medical Association (AMA) CPT Editorial Panel in late 2007, anticipating possible issuance of a new CPT code and positive national or regional Medicare coverage determinations in the first or second quarter of 2009. The Evidence-Based Medicine evaluation will be included in the application. If the CPT Editorial Panel concurs that a new CPT code is needed and appropriate, and we are able to demonstrate that MelaFind® is reasonable and necessary for the Medicare population, we anticipate that the new code would be referred to the AMA's Relative Value Scale Update Committee (RUC) to determine the appropriate level of Medicare Part B reimbursement for the procedure, relative to other physician services. This analysis would include a survey of physicians utilizing MelaFind® in the commercial setting. In setting Medicare reimbursement rates, CMS is generally guided, though not bound, by the recommendation of the RUC. Medicare coverage and payment policies significantly influence the practices and policies of private payors, managed care organizations, and state Medicaid agencies. We expect to commence efforts to obtain positive coverage decisions from private payors, managed care organizations, Medicaid agencies, and state Medicare administrative

contractors following the completion of the pivotal clinical trial or PMA submission. Presentations to the various committees that evaluate new technologies will be made. These will include the Evidence-Based Medicine evaluation and value proposition. We believe it is likely that the private payors, managed care organizations, and state Medicare administrative contractors will desire to establish pilot programs of MelaFind® to determine the impact of the product in their systems following PMA approval. In the case of private payors, managed care organizations and state Medicare administrative contractors, we anticipate that obtaining a positive coverage decision for MelaFind® may take at least 6 to 12 months following PMA approval.

One of the keys to securing reimbursement is the desire of physicians to use a new technology in order to enhance their diagnostic acumen and improve the standard of care. Likewise, we believe that once patients become aware of the availability of MelaFind®, they may demand that their physicians utilize MelaFind®. We believe that MelaFind® will represent an improvement in the standard of care for the detection of melanoma. As such, we anticipate that its adoption by physicians and reimbursement by payors will be facilitated by medical and scientific evidence published in peer-reviewed journals and presentations at scientific and medical meetings including the American Academy of Dermatology annual and regional meetings. We plan to execute a publication strategy and to provide information for continuing medical education efforts in order to communicate the potential of MelaFind® to improve patient care. We also plan to sponsor clinical trials following PMA approval in order to evaluate MelaFind® in additional settings. We anticipate that the results of these studies will also be published in peer-reviewed journals and presented at scientific and medical meetings. We anticipate that these studies will help to demonstrate the potential of MelaFind® to improve patient care.

We recognize that a favorable reimbursement environment will have a significant impact on MelaFind®'s adoption and commercial success. Even if a procedure is eligible for reimbursement, the level of reimbursement may not be adequate. In addition, third-party payors may deny reimbursement if they determine that the device used in the treatment was not cost-effective or was used for a non-approved indication. We have anticipated this need and have employed an active strategy to obtain medical coverage, identify appropriate coding and establish adequate payment.

Pending approval of a CPT code and the availability of third party reimbursement, we plan to offer MelaFind® to physicians, who would pay for using MelaFind®, and may or may not charge patients directly for its use. For example, in capitated systems such as certain managed care plans (where physicians cannot pass costs on to patients, but rather are paid a fixed amount per patient managed under the plan, whether or not treated) physicians may conclude that it is cost-effective to use MelaFind® in order to reduce utilization of other services such as biopsies, for example, when the MelaFind® result indicates biopsy is not recommended. In addition, we believe that roughly ten percent of all dermatological practices are focused on cosmetic dermatology. Most procedures performed in cosmetic dermatological practices and Medi-Spas are provided on a patient self-pay basis. Medi-Spas are health and beauty clubs and spas in which medical care and supervision by licensed medical practitioners such as doctors, nurses and physicians assistants is provided; they specialize in aesthetic medicine. We believe that healthcare consumers that seek these services are likely to pay for MelaFind®, as well.

Competition

We are not aware of any direct competitors to MelaFind®. A number of systems for visualization and assessment of pigmented skin lesions are in use or in development. These include clinical (naked eye) examination, whole body mole mapping systems, dermoscopes (also known as "dermatoscopes"), digital dermoscopes, spectrophotometric intercutaneous analysis (analysis of skin structures through measurement of how they absorb light of different wavelengths), confocal microscopy, and spectrophotometric (color) analysis. These systems rely on physician experience and expertise in recognizing patterns that are associated with melanoma and non-melanoma in order to render an interpretation and diagnosis.

The current primary method for detecting melanoma relies on physicians to interpret whether a pigmented skin lesion is suspicious for melanoma (thereby requiring biopsy) based on their ability to recognize patterns using clinical examination. Physicians use the "ABCDE" criteria, Asymmetry, Border irregularity, Color variation, Diameter greater than 6 mm, and Evolving in ABCD, in their assessment. Whole body mole mapping consists of periodic photography of patients, typically those at high risk for developing melanoma. The pictures are reviewed clinically. This service is

provided at some diagnostic imaging centers and dermatology offices. DigitalDerm, Inc. offers a computerized system for acquisition, storage, and review of the pictures.

Dermoscopy, or epiluminescence microscopy, allows for non-invasive visualization of colors and microstructures of the epidermis, the dermal-epidermal junction, and the papillary dermis not visible to the naked eye. Manufacturers of dermoscopes include (but are not limited to) Welch Allyn, Inc. (US), Heine Optotechnik (Germany), and 3Gen, LLC (US). Digital dermoscopes allow for dermoscopic images to be visualized on a computer screen at larger magnification. In addition, images may be stored and compared to images taken previously. Manufacturers of digital dermoscopes include (but are not limited to) Derma Medical Systems, Inc. (Austria), ZN Vision Technologies AG (Germany), Polartechnics, Ltd. (Australia), Linos Photonics, Inc. (Germany), and Biomips Engineering (Italy). Dermoscopy is a tool used by approximately 25% of dermatologists in the US and is associated with a long learning curve. Physicians experienced in the use of dermoscopy have been shown to have an increased diagnostic accuracy of 10 to 20% over clinical examination. Although some digital dermoscopes provide information regarding the probability that a lesion may be melanoma compared to a database of lesions, no system, to our knowledge, is under PMA development for objective interpretation.

A recent published article describes the results of a study utilizing the DB-Mips system from Biomips Engineering. The database of lesions used in this study differs significantly from our proprietary database. For example, our database includes a substantial number of lesions such as seborrheic keratoses and pigmented basal cell carcinomas, which can be difficult to differentiate from melanoma. The DB-Mips database included none of these lesions. Further, our database includes many more melanomas that are minimally invasive as well as a much higher percentage of dysplastic nevi compared to the DB-Mips database. Minimally invasive melanomas are more difficult to diagnose than melanomas that have significantly invaded the skin, and dysplastic nevi can be very difficult to differentiate from melanoma. Thus, we believe that the DB-Mips database does not include as many pigmented lesions that are difficult to differentiate from melanoma as our database. This is further confirmed by the fact that the specificity of dermatologists in other DB-Mips studies was reported to be over 80% while the specificity of dermatologists in MelaFind® studies is typically under 30%. The DB-Mips system has a reported specificity of up to 79%, which is roughly equivalent to the specificity of the dermatologists in DB-Mips studies. The DB-Mips system has a reported sensitivity to melanoma of about 95%. We believe that because the DB-Mips database includes relatively few early melanomas, direct comparison with MelaFind®'s sensitivity is not meaningful.

Spectrophotometric intercutaneous analysis is a technique of visualizing collagen, blood, and pigment. Astron Clinica (UK) manufactures a device utilizing this technique. Confocal microscopy is an experimental approach for non-invasive visualization of skin structures at the cellular level; such a device utilizing this technique is in development by Lucid (US).

A spectrophotometer (an instrument for measuring absorption of light of different wavelengths) is offered by Medical High Technologies S.p.A. (Switzerland). In contrast to MelaFind®, the product does not perform automatic quality control of images and has an external light source. We believe that the reported sensitivity of 80.4% would not gain market approval. Further, we are not aware of comparative data on physicians' performance in corresponding data sets. The system does not have PMA approval, nor are we aware of efforts directed to obtain PMA approval of the product.

The broad market for precision optical imaging devices used for medical diagnosis is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. If our products are approved for marketing, we will potentially be subject to competition from major optical imaging companies, such as General Electric Co., Siemens AG, Bayer AG, Eastman Kodak Company, Olympus Corporation, Carl Zeiss AG Deutschland and others, each of which manufactures and markets precision optical imaging products for the medical market and could decide to develop or acquire a product to compete with MelaFind®.

Manufacturing

We are currently focusing our manufacturing efforts on hardware engineering in order to make the functioning of the MelaFind® hand-held imaging devices more consistent and robust, and to facilitate larger-scale manufacturing methods of the pre-commercialization devices that will be used in the pivotal clinical trial. Data from the clinical studies as well as

from engineering tests under stress and different environmental conditions are being used to refine appropriate manufacturing and field specifications before the design is fixed.

For this crucial phase in development, we have contracted with a third-party vendor, ASKION (Gera, Germany), which specializes in precision optics. We are currently negotiating with Carl Zeiss Jena (Jena, Germany), an international optics house, to supply lenses to ASKION to be used in post-clinical trial models of the hand-held clinical units. The pre-commercialization hand-held imaging devices to be assembled by ASKION are expected to be available for pivotal trial initiation planned for early 2006. The pre-commercialization hand-held imaging devices are expected to be more robust while having at least the same or better performance than the hand-held imaging devices used in the clinical program to date.

We have recently been inspected by the FDA for the manufacturing and commercialization of DIFOTI®, our dental cavities detection product that has been discontinued for business reasons. The FDA inspectors observed deficiencies that were documented on FDA Form 483 that was issued to us following the inspection. We have had a follow-up meeting with the FDA and are working with the FDA and consultants to address the inspectional findings, particularly as they relate to current MelaFind® design development and ultimate MelaFind® commercial manufacturing. We believe that the issues can be addressed to the satisfaction of the FDA and will not materially adversely effect our operations.

Research and Development Efforts

Our research and development efforts are currently focused on finalization and validation of the pre-commercialization hand-held imaging device, and completion of the development of the MelaFind® *Lesion Classifiers*. To date, we have developed and tested four-step classifiers (see “Results of Training Studies and Blinded Tests”), and we are currently working on five-step versions. The classifiers have been trained on 113 melanomas to date, and our goal is to use 300 melanomas (and over 4,000 non-melanoma pigmented lesions) for training. To date we have collected approximately 268 melanomas, which are available for classifier training.

We have engaged Battelle Memorial Institute to perform specific technical services supporting our algorithm and software development and other efforts.

Our R&D plan also includes further improvements such as incorporating wireless technology and an internet connection for hand-held imaging device quality monitoring, as well as faster and easier software downloads for future software versions. The internet based monitoring of the performance of our hand-held imaging device, known as Intelligent Device Management, is intended to enable us to continuously monitor our hand-held imaging device, advise the user of errors in handling, and thus enhance customer satisfaction and loyalty.

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

Following commercialization of MelaFind®, we intend to evaluate the potential use of our light based computer vision platform in other applications, including the non-invasive detection of basal cell carcinoma, the most common skin cancer. New hardware systems for the imaging of blood and blood vessel patterns are needed since the majority of basal cell carcinomas are not pigmented and, accordingly, the MelaFind® system as currently developed is not appropriate for this use. However, we believe MelaFind®’s software programs and algorithms will be applicable.

Intellectual Property

Our policy is to protect our intellectual property by obtaining US and foreign patents to protect technology, inventions and improvements important to the development of our business. To date we have been awarded 14 US patents with numerous foreign counterparts, of which six US patents and two Australian patents relate to various aspects of

MelaFind®. In addition, we have applied for two additional US patents and have filed certain foreign patent applications relating to MelaFind®, of which two foreign patent applications are currently in the European regional phase. Also, we have obtained non-exclusive licenses from several of our suppliers for critical components of MelaFind®. We have not granted any significant licenses with respect to our intellectual property.

We cannot be certain that our patents will not be challenged or circumvented by competitors. Whether a patent is infringed and is valid, or whether a patent application should be granted, are all complex matters of science and law, and therefore we cannot be certain that, if challenged, our patents, patent applications and/or other intellectual property rights would be upheld. If one or more of those patents, patent applications and other intellectual property rights are invalidated, rejected or found unenforceable, that could reduce or eliminate any competitive advantage.

We also rely on trade secrets and technical know-how in the manufacture and marketing of MelaFind®. We require our employees, consultants and contractors to execute confidentiality agreements with respect to our proprietary information.

We have obtained US trademark registrations for the following marks: “MelaFind®” and “DIFOTI®,” as well as the corporate logo for “eos-electro-optical sciences, inc.®” The goods covered by these registrations are in International Class 010 and US Classes 26, 39 and 44. For MelaFind®, the description of goods and services covered by the trademark is: “medical devices, namely, electro-optical devices incorporating hardware for obtaining images in different spectral bands and software for analyzing the images for use in analyzing skin lesions and determining the existence of melanoma.” For DIFOTI®, the description of goods and services covered by the trademark is: “electro-optical apparatus to diagnose dental conditions.” For “eos-electro-optical sciences, inc.®,” the description of goods and services covered by the trademark is: “instrumentation comprising computer assisted optical imagers and image analyzers for use in the detection of dental cavities, cutaneous melanoma, and other pathologies of the teeth, skin and other tissues.” We also have registered the internet domain names: www.eo-sciences.com, www.eosciences.com, www.melafind.com, www.difoti.com, www.smartlightsensors.com, and www.skinsurf.com.

The following table lists the fundamental US patents that cover the MelaFind® methodology, apparatus, and systems:

US Patents Relating to MelaFind®

Patent #	Title	Issued	Expiration
6,081,612	Systems and Methods for the Multispectral Imaging and Characterization of Skin Tissue	06/27/00	02/27/17
6,208,749	Systems and Methods for the Multispectral Imaging and Characterization of Skin Tissue	03/27/01	02/27/17
6,307,957	Multispectral Imaging and Characterization of Biological Tissue	10/23/01	02/27/17
6,626,558	Apparatus for Uniform Illumination of an Object	09/30/03	08/31/21
6,657,798	Method for Optimizing the Number of Good Assemblies Manufacturable From a Number of Parts	12/02/03	02/10/23
6,710,947	Method for Assembling Lens Elements	03/23/04	02/27/23

The first two listed patents improve the specificity and sensitivity of the software algorithms that classify lesions as suspicious for melanoma or as not suspicious. The third patent extends the prior patents for potential use in evaluating gastro-intestinal lesions. The fourth patent covers a novel way of providing illumination with which to capture images. The fifth and sixth patents describe cost-saving methods of lens assembly. We believe that our patented methods and apparatus, together with unpatented related trade-secret technology, give us a competitive advantage; however, we cannot be certain that, if challenged, our patented methods and apparatus and/or trade-secret technology would be upheld. If one or more of our patented methods, patented apparatus or trade secret technology rights are invalidated, rejected or found unenforceable, that could reduce or eliminate any competitive advantage we might otherwise have had.

US patent No. 6,081,612 relates to the MelaFind® system and methods employed in building MelaFind® classification algorithms involving the use of novel multi-spectral lesion features by means of wavelet maxima representations. Wavelet maxima representations use specific types of mathematical transformations called wavelets to represent a signal, such

as an image of a lesion taken by the MelaFind® system, at different detail levels. The wavelet maxima representation retains information of potential diagnostic value. This information is quantified in the form of statistical features used for automatic classification. Patent No. 6,208,749 relates to methods employed in building MelaFind® classification algorithms involving the use of novel features of multispectral lesion images that do not involve the use of wavelet transformations to determine whether the lesion is or is not a melanoma. We believe the inclusion of the described wavelets and non-wavelets features improves significantly the sensitivity and specificity of the melanoma classifiers. Patent No. 6,307,957 extends the use of the novel features of the MelaFind® system to endoscopy (examination of gastro-intestinal tissues using fiber-optic probes). We have no present plans to develop endoscopy applications of our technology.

Patent 6,626,558 covers the array of numerous light-emitting diodes (LED's) that are used in the MelaFind® hand-held device to provide uniform illumination of lesions in multiple spectral bands of illumination. Patent 6,657,798 involves the use of a computer algorithm to optimize the number of lens assemblies possible from a given number of sets of lens elements. Patent 6,710,947 describes a method for the economical assembly of the nine elements of the MelaFind® hand-held device's optical lens apparatus.

We also have developed trade secret calibration methods, classifier programs, and search engines; these programs have been developed over many years and incorporate decades of experience in optical computer vision. In addition, our proprietary MelaFind® database of over 5,000 lesions has been compiled over a number of years and would be difficult to replicate.

FDA Regulation

Our product, MelaFind®, is regulated as a medical device and is subject to extensive regulation by the FDA and other regulatory authorities in the US. The FD&C Act and other federal and state statutes and regulations govern the research, design, development, preclinical and clinical testing, manufacturing, safety, approval or clearance, labeling, packaging, storage, record keeping, servicing, promotion, import and export, and distribution of medical devices.

Unless an exemption applies, each medical device we wish to commercially distribute in the US will require either prior premarket notification, or 510(k) clearance, or PMA approval, from the FDA. The FDA classifies medical devices into one of three classes. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are subject to general controls such as labeling, premarket notification, and adherence to the FDA's QSR. Class II devices are subject to special controls such as performance standards, postmarket surveillance, FDA guidelines, as well as general controls. Some Class I and Class II devices are exempted by regulation from the premarket notification, or 510(k), clearance requirement or the requirement of compliance with certain provisions of the QSR. Devices are placed in Class III, which requires approval of a PMA application, if insufficient information exists to determine that the application of general controls or special controls are sufficient to provide reasonable assurance of safety and effectiveness, or they are life-sustaining, life-supporting or implantable devices, or the FDA deems these devices to be "not substantially equivalent" either to a previously 510(k) cleared device or to a "preamendment" Class III device in commercial distribution before May 28, 1976, for which PMA applications have not been required. The FDA classifies MelaFind® as a Class III device, requiring PMA approval.

A PMA application must be supported by valid scientific evidence, which typically requires extensive data, including technical, pre-clinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. A PMA application must include, among other things, a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. A PMA application also must be accompanied by a user fee, unless exempt. For example, the FDA does not require the submission of a user fee for a small business's first PMA. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information, or clarification of information already provided. Also during the review period, the FDA has informed us that an advisory panel of experts from outside the FDA will be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with

the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures.

We commenced the PMA application process for MelaFind® by filing a proposed Shell (an outline of a PMA) for a three module PMA on September 30, 2002. We filed as a Small Business Entity exempt from the user fee requirement. The Shell was accepted and two Modules have been filed and reviewed. The third Module will include the results of the pivotal clinical study, and cannot be filed until after that study is complete and its results have been evaluated. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

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

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter, or approvable letter, which usually contains a number of conditions which must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device for certain indications. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed while the trials are conducted and the data acquired is submitted in an amendment to the PMA. Even with additional trials, the FDA may not approve the PMA application. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling and device specifications, materials or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical trials are almost always required to support a PMA application, and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an IDE to the FDA. We have not been required to file an IDE application for the MelaFind® clinical studies because FDA has considered the trials "non-significant risk" (NSR) studies subject to abbreviated IDE regulations, which do not require formal IDE submission. An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent form are approved by appropriate institutional review boards at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. As stated above, the clinical studies of MelaFind® are considered by the FDA as NSR. Consequently, the trials are conducted under the auspices of an abbreviated IDE. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any

of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application, or 510(k) clearance, for numerous reasons, including, but not limited to, the following:

- the FDA, other regulatory authorities, or an IRB do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- physicians do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- patients experience adverse events;
- IRBs and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, GCPs or other FDA requirements;
- 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 may, 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.

Our clinical trials may not generate favorable data to support any PMA applications, and we may not be able to obtain such approvals on a timely basis, or at all. Delays in receipt of or failure to receive such approvals, the withdrawal of previously received approvals, or failure to comply with existing or future regulatory requirements would have a material adverse effect on our business, financial condition and results of operations. Even if granted, the approvals may include significant limitations on the intended use and indications for use for which our products may be marketed.

After a device is approved or cleared and placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act that may present a risk to health.

Also, the FDA may require us to conduct postmarket surveillance studies or order us to establish and maintain a system for tracking our products through the chain of distribution to the patient level. The FDA enforces regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors. Thus, we must continue to spend time, money, and effort to maintain compliance.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of our clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters;
- fines and civil penalties;

- unanticipated expenditures;
- delays in approving or refusal to approve our applications, including supplements;
- withdrawal of FDA approval;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

We and our contract manufacturers, specification developers, and some suppliers of components, are also required to manufacture our products in compliance with cGMP requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA enforces the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. We expect that our manufacturing facility and those of our subcontractors will be subject to domestic and international regulatory inspection and review. If the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business. We cannot assure you that we will be able to comply with all applicable FDA regulations.

Government Regulation

The advertising of our MelaFind® product will be subject to both FDA and Federal Trade Commission regulations. In addition, the sale and marketing of MelaFind® will be subject to a complex system of federal and state laws and regulations intended to deter, detect, and respond to fraud and abuse in the healthcare system. These laws and regulations restrict and may prohibit pricing, discounting, commissions and other commercial practices that may be typical outside of the healthcare business. In particular, anti-kickback and self-referral laws and regulations will limit our flexibility in crafting promotional programs and other financial arrangements in connection with the sale of our products and related services, especially with respect to physicians seeking reimbursement through Medicare or Medicaid. These federal laws include, by way of example, the following:

- the anti-kickback statute prohibits certain business practices and relationships that might affect the provision and cost of healthcare services reimbursable under Medicare, Medicaid and other federal healthcare programs, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs;
- the physician self-referral prohibition, commonly referred to as the Stark Law, which prohibits referrals by physicians of Medicare or Medicaid patients to providers of a broad range of designated healthcare services in which the physicians or their immediate family members have ownership interests or with which they have certain other financial arrangements;
- the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program;
- the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and

- the Civil Monetary Penalties Law, which authorizes HHS to impose civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. These laws also impose an affirmative duty on those receiving Medicare or Medicaid funding to ensure that they do not employ or contract with persons excluded from the Medicare and other government programs.

Many states have adopted or are considering legislative proposals similar to the federal fraud and abuse laws, some of which extend beyond the Medicare and Medicaid programs to prohibit the payment or receipt of remuneration for the referral of patients and physician self-referrals regardless of whether the service was reimbursed by Medicare or Medicaid. Many states have also adopted or are considering legislative proposals to increase patient protections, such as limiting the use and disclosure of patient-specific health information. These state laws typically impose criminal and civil penalties similar to the federal laws.

In the ordinary course of their business, medical device manufacturers and suppliers have been and are subject regularly to inquiries, investigations and audits by federal and state agencies that oversee these laws and regulations. Recent federal and state legislation has greatly increased funding for investigations and enforcement actions, which have increased dramatically over the past several years. This trend is expected to continue. Private enforcement of healthcare fraud also has increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. These whistleblower suits by private persons, known as *qui tam* relators, may be filed by almost anyone, including physicians and their employees and patients, our employees, and even competitors. HIPAA, in addition to its privacy provisions, created a series of new healthcare-related crimes.

Environmental Regulation

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We and our investigators and vendors are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

International Regulation

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country from having no regulations to having a premarket notice or premarket acceptance. The time required to obtain approval in a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, US, Canada and various other industrialized countries.

The European Union, which includes most of the major countries in Europe, has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third party assessment by a

"Notified Body." This third party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. As part of the CE compliance, manufacturers are required to comply with the ISO 9000 series of standards for quality operations (an international standard for quality management requirements maintained by the International Organization for Standardization (ISO)). Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Outside of the European Union, regulatory approval needs to be sought on a country-by-country basis in order for us to market our products.

Product Liability and Insurance

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if MelaFind® causes, or merely appears to have caused, an injury. Claims may be made by patients, healthcare providers or others involved with MelaFind®. MelaFind® will require from the FDA approval prior to commercialization in the US. The clinical studies of MelaFind® are considered by the FDA as NSR. Consequently, the trials are conducted under the auspices of an abbreviated IDE. We therefore do not maintain domestic clinical trial liability insurance. We have placed clinical trial liability insurance in certain European countries where required by statute or clinical site policy. Although we have general liability insurance that we believe is appropriate, and anticipate obtaining adequate product liability insurance before commercialization of MelaFind®, this insurance is and will be subject to deductibles and coverage limitations. Our anticipated product liability insurance may not be available to us in amounts and on acceptable terms, if at all, and, if available, the coverages may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business.

Employees

As of June 30, 2005, we had 27 full-time and two part-time employees, of whom 13 were engaged in research and development (including clinical and regulatory affairs), seven in production (including document control and quality assurance) and nine in marketing, sales and administrative activities. We believe that our relationship with our employees is good.

Facilities

We lease approximately 2,800 square feet of office space at 3 West Main Street, Suite 201, Irvington, New York, and an additional 3,700 square feet of office, laboratory, and assembly space in an adjacent building with the street address of 1 Bridge Street, Suite 15, Irvington, New York. The lease on the 2,800 square feet of space expires in November 2010. The lease on the 3,700 square feet of space expires in June 2009. We believe that these facilities are adequate to meet our current and reasonably foreseeable requirements. We believe that we will be able to obtain additional space, if required, on commercially reasonable terms.

Legal Proceedings

We are not currently a party to any legal proceedings.

Discontinued Business

As of April 5, 2005, we decided to discontinue all operations associated with our DIFOTI® product, a non-invasive imaging device for the detection of dental cavities, in order to focus our resources on the development and commercialization of MelaFind®. We are currently seeking an acquirer for the DIFOTI® assets. Once a disposition relating to the DIFOTI® assets is complete, we do not expect to have any significant continuing responsibility for the DIFOTI® business.

Management

Executive Officers and Directors

The following table sets forth the names, ages as of August 31, 2005 and a brief account of the business experience of each person who is a current executive officer or director of our company and each person who has been elected to serve as a director effective upon the close of this offering. Each director of our company will hold office until the next annual meeting of shareholders of our company or until his successor has been elected and qualified.

Name	Age	Position
Joseph V. Gulfo, M.D.	42	Director, President and Chief Executive Officer
Karen Krumeich	52	Vice President, Finance, Chief Financial Officer and Treasurer
Jon I. Klippel	52	Vice President, Marketing and Sales
William R. Bronner	59	Vice President, Legal Counsel and Compliance
Breaux Castleman(1)(2)	65	Director, Chairman of the Board of Directors
Sidney Braginsky(1)	68	Director
George C. Chryssis(1)	58	Director
Martin D. Cleary(2)(3)(4)	60	Director Elect
Dan W. Lufkin(2)(3)	74	Director
Gerald Wagner, Ph.D.	62	Director

(1) Member of Compensation Committee

(2) Member of Nominating and Governance Committee

(3) Member of Audit Committee

(4) Director elected to serve effective as of the completion of this offering

Executive Officers

Joseph V. Gulfo, M.D., M.B.A. has served as our President and Chief Executive Officer and a member of our board of directors since January 2004. From May 1999 to November 2004, he served as Chairman, Chief Executive Officer and President of Antigen Express, Inc., a development-stage company developing immunodiagnostics and therapeutics for cancer. Dr. Gulfo serves as a director of ProCertus BioPharm, Inc., a privately-held company. Dr. Gulfo received a B.S. in Biology from Seton Hall University, an M.D. from the University of Medicine and Dentistry of New Jersey and an M.B.A. in Finance from Seton Hall University.

Karen Krumeich has served as our Vice President, Finance and Chief Financial Officer since January 2005 and Treasurer since May 2005. From August 2004 to January 2005 she served as a financial consultant with Horn Murdock Cole, a financial consulting firm. From September 2002 to July 2004, she served as divisional Chief Financial Officer of the hospital group division of Henry Schein, Inc., a publicly-held medical and dental products distributor. From March 2000 to August 2002, she served as a financial consultant with Consulting Associates, a financial consulting firm. Ms. Krumeich received her B.S. in Pharmacy from the University of Toledo College of Pharmacy and completed additional coursework in accounting at Cleveland State University.

Jon I. Klippel has served as our Vice President, Marketing and Sales since December 2004. From April 2004 to November 2004, he was a marketing and sales consultant. From January 2003 to March 2004, he served as Senior Marketing Manager of PDI, Inc., a publicly-traded company offering outsourced marketing, sales and sale support services to biopharmaceutical and medical device companies. From February 2002 to December 2002, he was a marketing and sales consultant. From July 2000 to February 2002, he served as Director of Marketing and Business Development at National Imaging Associates, Inc., a privately-held diagnostic imaging management company. Mr. Klippel received a B.A. in Political Science from Albright College and an M.B.A. from Rutgers University Graduate School of Business.

William R. Bronner has served as our Vice President, Legal Counsel and Compliance since July 2000 and as our Secretary since May 2002. From 1986 to July 2000, Mr. Bronner served as Vice President, General Counsel and Secretary of Kronos, Inc. Mr. Bronner received a B.A. in Government from Dartmouth College and a J.D. from Columbia University Law School.

Our executive officers are elected by, and serve at the discretion of our board of directors. There are no family relationships between our directors and executive officers.

Non-Executive Directors

Breaux Castleman has served as a member of our board of directors and Chairman of our board since July 2003. Since August 2001, he has served as President, Chief Executive Officer and Chairman of Syntiro Healthcare Services, Inc. Mr. Castleman also serves as a director of FemPartners, Inc., Integrated Diagnostic Centers, Inc. and Radiology Practice Management, Inc., each of which are privately-held companies. From December 1999 to July 2001, he served as Chief Executive Officer of Physia Corp. He served as President of Scripps Clinic from July 1996 to October 1999. He holds a B.A. in economics from Yale University and attended New York University Graduate School of Business Administration.

Sidney Braginsky has served as a member of our board of directors since 2001. He also currently serves as the Chairman and Chief Executive Officer of Digilab, LLC (a spectroscopy instruments manufacturer), Chief Executive Officer and President of Ineedmd, Ltd., Chairman of Double D Venture Fund, LLC, Chairman of the Board of the City University of New York Robert Chambers Laboratory and Trustee on the Boards of Long Island High Tech Incubator and the Long Island Museum of Science and Technology. He formerly served as President of Olympus America and Mediscience Corp., Chairman of Atropos Technologies, LLC and International Standards Organization Optics, and a director for Noven Pharmaceuticals, Inc. Mr. Braginsky received his B.S. in biology from Queens College.

George C. Chryssis has served as a member of our board of directors since 2001. Since 2003, he has served as President, Chief Executive Officer and Chairman of the Board of MISTsoft Corp., a privately-held software company which he founded. Since 2000, he has served as the Managing Member of Arcadian Capital Management, LLC, and General Partner of Arcadian Venture Partners, LP, a venture capital firm with investments in early stage technology companies, including EOS. Since 2003, he has also served as Chairman of the Board of Directors of DelCom Corp., a privately-held telecommunications software company. Mr. Chryssis received a B.S. and M.S. in electrical engineering from Northeastern University.

Martin D. Cleary will become a member of our board of directors upon completion of this offering. Since February 2003, he has served as the President and Chief Executive Officer of Juvaris Biotherapeutics, Inc., a company engaged in the development of therapeutic vaccines for cancer and infectious diseases. From September 1999 to May 2002, he served as the President and Chief Executive Officer of Genteric, Inc., a company engaged in non-viral gene delivery. Mr. Cleary received a B.S. in accounting from Rutgers University in 1971, and a certificate in international studies from Columbia University in 1973.

Dan W. Lufkin has served as a member of our board of directors since July 2003. He is also a co-founder and former Chairman of the investment banking firm, Donaldson, Lufkin & Jenrette, Inc. Mr. Lufkin currently serves as a consultant to and/or board member of a number of private companies and non-profit endeavors. Mr. Lufkin received a B.A. degree from Yale University and an M.B.A. from Harvard Business School.

Gerald Wagner, Ph.D. was appointed as a member of our board of directors in May 2005. Since 2002, he has owned and operated Gerald Wagner Consulting LLC, an international consulting company specializing in: international project management; technology and application consulting; and company assessments. From March 1992 to September 2003, he was a Senior Vice President, Lab Testing Systems, at Bayer, Inc. Dr. Wagner received a Masters and Ph.D. in electro-mechanical design from Technical University, Darmstadt, Germany.

Board of Directors Composition

Our current charter documents and the charter documents we expect to be in effect upon completion of this offering authorize up to nine (9) directors. We currently have six (6) directors and expect to have seven (7) directors upon completion of the initial public offering. Joseph V. Gulfo, M.D., Breaux Castleman, Dan W. Lufkin and George C.

Chryssis were elected pursuant to voting provisions contained in a voting agreement that we entered into with certain holders or our common stock and preferred stock. Upon the closing of this offering, the voting agreement will be terminated and none of our stockholders will have any special rights regarding board representation. See “Related party transactions — Voting Agreement” for additional information regarding the voting agreement.

Board Committees

Audit Committee. The current members of our audit committee are Messrs. Braginsky and Lufkin, each of whom we believe satisfies the independence requirements of the NASDAQ Capital Market and the SEC. Mr. Cleary will join the audit committee upon completion of the offering and will chair the committee. We believe Mr. Cleary satisfies the independence requirements of the NASDAQ Capital Market and the SEC. In addition, we believe Mr. Cleary is qualified as an audit committee financial expert under the regulations of the SEC, and has the accounting and related financial management expertise required by the NASDAQ Capital Market. Our audit committee assists our board in its oversight of:

- the integrity of our financial statements;
- our independent registered public accounting firm’s qualifications and independence; and
- the performance of our independent auditors.

The audit committee has the sole and direct responsibility for appointing, evaluating and retaining our independent registered public accounting firm and for overseeing their work. All audit services to be provided to us and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent auditors must be approved in advance by our audit committee.

Compensation Committee. The members of our compensation committee are Messrs. Castleman, Braginsky and Chryssis, each of whom we believe satisfies the independence requirements of the NASDAQ Capital Market and the SEC. Mr. Castleman chairs this committee. The purpose of our compensation committee is to discharge the responsibilities of our board of directors relating to compensation of our executive officers. Specific responsibilities of our compensation committee include:

- reviewing and recommending compensation of our executive officers;
- administering our stock incentive plans; and
- reviewing and recommending incentive compensation and equity plans.

Nominating and Governance Committee. The members of our nominating and governance committee are Messrs. Lufkin and Castleman, each of whom we believe satisfies the independence requirements of the NASDAQ Capital Market. Mr. Lufkin will chair this committee. Mr. Cleary will join the nominating and governance committee upon completion of the offering. Our nominating and governance committee:

- identifies and recommends nominees for election to our board of directors;
- develops and recommends our corporate governance principles; and
- oversees the evaluation of our board of directors and management.

Compensation Committee Interlocks and Insider Participation

We did not have a compensation committee until May 2005. Dr. Gulfo, our Chief Executive Officer, previously participated in the deliberations regarding executive compensation. None of our executive officers has served as a member of the compensation committee, or other committee serving an equivalent function, of any other entity, one of whose executive officers served as a member of our compensation committee.

Election of Directors

The number of directors is determined by the stockholders at their annual meeting, subject to the right of the stockholders to change such number between annual meetings and to the right of our board to increase such number between annual meetings.

Director Compensation

After completion of this offering, in addition to reimbursement of expenses incurred in attending meetings of our board of directors and committees of our board, our non-employee directors will receive an annual fee of $10,000 for serving as directors and an additional $500 per meeting for each meeting attended, whether in person or by telephone. In addition, after completion of this offering, the chairman of our board of directors, the chairman of our audit committee and the chairman of our nominating and governance committee will each receive an annual fee of $10,000. After completion of this offering, each member of our board who is not a company employee will receive an annual stock option grant to purchase up to 5,000 shares of common stock. Such stock options will vest in full upon the first anniversary of issuance and have an exercise price equal to the fair market value of our common stock on the date of the grant. In addition, we reimburse each member of our Board who is not a company employee for reasonable travel and other expenses in connection with attending meetings of the Board.

Scientific and Medical Advisory Committee

We have established a Scientific and Medical Advisory Committee made up of leading experts in the fields of dermatology and oncology. Members of our Scientific and Medical Advisory Committee consult with us regularly on matters relating to:

- our research and development programs;
- the design and implementation of our clinical trials;
- market opportunities from a clinical perspective;
- new technologies relevant to our research and development programs; and
- scientific and technical issues relevant to our business.

The current members of our Scientific and Medical Advisory Committee are:

Name	Professional Affiliation
Jeffrey P. Callen, M.D.	Professor and Chief of the Division of Dermatology, University of Louisville School of Medicine; Member of the Board of Directors of the American Board of Dermatology, Inc.
Armand B. Cognetta, Jr., M.D.	Dermatologist in private practice with Dermatology Associates of Tallahasee; Member, American Academy of Dermatology; former President of Florida Society of Dermatology; former President of Dermatology Photography Society.
Robert Friedman, M.D.	Clinical Assistant Professor, Department of Dermatology, New York University School of Medicine; Past Director, American Cancer Society, New York City Division, and Member, Professional Education Committee; American Academy of Dermatology: Member, Skin Cancer/ Melanoma Committee, Past Chairman, Industry Liaison Committee.
Martin C. Mihm, Jr., M.D., Chairman	Professor and Chief of Dermatopathology at Harvard Medical School; Chief of Dermatopathology at Massachusetts General Hospital; Co-Director of the Pigmented Skin Lesion Clinic at Massachusetts General Hospital; Co-Chairman of the Melanoma Pathology Program of the World Health Organization; Co-Director of the Rare Tumor Institute of the World Health Organization; member of the editorial and advisory board of the American Journal of Dermatopathology and the International Journal of Surgical Pathology; Member of the American Academy of Dermatology; New England Pathology Society; American Society of Dermatopathology; American Society of Clinical Oncology; and College of American Pathologists.

Name	Professional Affiliation
Harold S. Rabinovitz, M.D.	Dermatologist in private practice with Skin and Cancer Associates in Plantation, Florida; Voluntary Professor of Dermatology at the University of Miami-School of Medicine; Associate Editor of the Journal of Dermatologic Surgery; member of the Board of Directors of the South Florida Dermatology Foundation.
Darrell S. Rigel, M.D.	Clinical Professor of Dermatology, New York University Medical Center; Secretary and Treasurer of the American Dermatological Association; Past President, American Academy of Dermatology; Member, Board of Directors of the American Cancer Society New York City Division and Chairman of its Subcommittee on Skin Cancer.

Medical Advisor and Liaison to Our Board of Directors

Robert Friedman, M.D., a member of our Scientific and Medical Advisory Committee, serves as a medical advisor to our board of directors and a liaison between our Scientific and Medical Advisory Committee and our board of directors. See “Consulting Agreements — Consulting Agreement with Robert Friedman, M.D.”

Executive Compensation

The following table sets forth summary compensation information for the years ended December 31, 2002, December 31, 2003 and December 31, 2004 for our chief executive officer and each of our two other most highly compensated executive officers whose salary and bonus for 2004 was more than $100,000. As of December 31, 2004, there were no other persons serving as executive officers. We have also included summary compensation information for two executive officers who would have been among the four other most highly compensated executive officers whose salary and bonus for 2004 would have been more than $100,000 had they served as executive officers for the full year. We refer to these officers collectively as our named executive officers.

Summary Compensation Table

		Annual compensation		Long term compensation	
Name and principal position	**Year**	**Salary ($)**	**Bonus ($)**	**Securities underlying options**	**All other compensation**
Joseph V. Gulfo, M.D.	2004	$ 173,656	—	81,753(1)	$ 19,880(1)
President and Chief	2003	—	—	—	—
Executive Officer	2002	—	—	—	—
Marek Elbaum, Ph.D.	2004	173,549	—	10,000	—
Founder and former Chief Science	2003	81,085	—	29,071	—
and Technology Officer	2002	30,204	—	—	—
William Bronner	2004	132,612	—	37,000	—
Vice President, Legal Counsel	2003	106,255	—	32,161	—
and Compliance	2002	26,444	—	1,875	—
Karen Krumeich(2)	2004	—	—	60,000	—
Vice President Finance, Chief	2003	—	—	—	—
Financial Officer	2002	—	—	—	—
Jon I. Klippel(3)	2004	9,346	—	45,000	—
Vice President Marketing	2003	—	—	—	—
and Sales	2002	—	—	—	—

(1) Dr. Gulfo has been granted another stock option which is not reflected in this table because the number of shares purchasable under the option can only be calculated at the time of PMA approval of MelaFind®. The number of shares granted under this option is equal to that number of shares of our common stock equal to four percent of our fully-diluted capital stock at that time of PMA approval of MelaFind® minus 81,753 shares of our common stock. The exercise price of this option is $0.46 per share.

(2) Ms. Krumeich’s employment with us began in January 2005 at an annual salary of $165,000.

(3) Mr. Klippel’s employment with us began in December 2004 at an annual salary of $135,000.

Stock Options Granted in 2004

The following table provides information regarding stock options granted during 2004 to the named executive officers in that period. We have not granted any stock appreciation rights.

Name	Number of securities underlying options granted	% of total options granted to employees in fiscal year	Exercise or base price per share(1)	Expiration date	Potential realizable value of assumed annual rates of stock price appreciation for option term(2)	
					5%	10%
Joseph V. Gulfo, M.D.(3)	75,227	11.07%	$ 0.46	2/02/09	$ 445,450	$ 571,165
	6,526	0.09	0.46	2/02/09	38,643	49,549
Marek Elbaum, Ph.D.(4)	10,000	1.47	0.46	2/02/09	59,214	75,926
Karen Krumeich	60,000	8.82	0.46	12/17/09	355,284	455,553
William R. Bronner	17,000	2.50	0.46	2/02/09	100,664	129,073
	20,000	2.94	0.46	12/17/09	118,428	151,851
Jon I. Klippel	45,000	6.62	0.46	12/17/09	266,463	341,665

(1) Exercise price is equal to the fair market value on the date of grant as determined by our board of directors.

(2) The dollar amounts under these columns are the result of calculations at rates set by the SEC and, therefore, are not intended to forecast possible future appreciation, if any, in the price of the underlying common stock. The potential realizable values are calculated based on the initial public offering price of $5.00 per share, and assuming that the market price appreciates from this price at the indicated rate for the entire term of each option and that each option is exercised and sold on the last day of its term at the assumed appreciated price. Actual gains, if any, on stock option exercises depend on the future performance of the common stock and overall stock market conditions. The amounts reflected in the following table may not necessarily be achieved.

(3) Dr. Gulfo has been granted another stock option which is not reflected in this table because the number of shares purchasable under the option can only be calculated at the time of PMA approval of MelaFind®. The number of shares granted under this option is equal to that number of shares of our common stock equal to four percent of our fully-diluted capital stock at that time of PMA approval of MelaFind® minus 81,753 shares of our common stock.

(4) Formerly our Chief Science and Technology Officer.

Aggregated Option Exercises in 2004 and Year-End Option Values

The following table provides information about the number of shares issued upon option exercises by our named executive officers as of December 31, 2004 and the value realized by our named executive officers. The table also provides information about the number and value of options held by our named executive officers at December 31, 2004.

Name	Number of unexercised securities underlying options at December 31, 2004		Value of unexercised in-the-money options at December 31, 2004(1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Joseph V. Gulfo, M.D.(2)	71,535	10,218	$ 324,769	$ 46,390
Marek Elbaum, Ph.D.(3)	14,070	25,000	56,280	114,500
Karen Krumeich	0	60,000	—	272,400
William R. Bronner	49,160	21,875	205,980	98,219
Jon I. Klippel	0	45,000	—	204,300

(1) There was no public trading market for our common stock as of December 31, 2004. Accordingly, as permitted by the rules of the SEC, we have calculated the value of unexercised in-the-money options based on the initial public

offering price of $5.00 per share, less the aggregate exercise price, without taking into account any taxes that might be payable in connection with the transaction.

(2) Dr. Gulfo has been granted another stock option which is not reflected in this table because the number of shares purchasable under the option can only be calculated at the time of PMA approval of MelaFind®. The number of shares granted under this option is equal to that number of shares of our common stock equal to four percent of our fully-diluted capital stock at that time of PMA approval of MelaFind® minus 81,753 shares of our common stock.

(3) Formerly our Chief Science and Technology Officer.

Equity Compensation Plans

2005 Stock Incentive Plan

In 2005, we adopted our 2005 Stock Incentive Plan (2005 Plan). The 2005 Plan permits the granting of awards to key employees, directors, officers, consultants and scientific collaborators in the form of incentive or nonqualified stock options and equity-based awards. Stock options granted under the 2005 Plan may be "incentive stock options" meeting the requirements of Section 422 of the Code or nonqualified stock options, which do not meet the requirements of Section 422. Stock awards granted under the 2005 Plan to eligible participants may take the form of the issuance and transfer to the recipient of shares of common stock or a grant of stock units representing a future right to such shares of common stock. As of the date of this offering, there are 1,000,000 shares of our common stock authorized and reserved for issuance upon exercise of options which may be granted under the 2005 Plan and no options or other equity based awards have been issued under the 2005 Plan. Pursuant to the 2005 Plan on each of January 1, 2006 and January 1, 2007, the number of shares of common stock authorized for issuance will be automatically increased by an amount equal to 3% of the then outstanding shares of common stock unless the board decides to reduce the amount of the increase.

2003 Stock Incentive Plan

In 2003, we adopted our 2003 Stock Incentive Plan, as amended (2003 Plan). The 2003 Plan permitted the granting of awards to our employees and other key persons (including directors, officers, consultants and scientific collaborations) in the form of restricted stock, and incentive or nonqualified stock options. Stock options granted under the 2003 Plan may be "incentive stock options" meeting the requirements of Section 422 of the Code or nonqualified stock options which do not meet the requirements of Section 422. As of August 31, 2005, options to purchase 639,697 shares of our common stock are outstanding under the 2003 Plan. No options or other equity-based awards have been granted under the 2003 Plan since the adoption of the 2005 Plan, and no further options or other equity-based awards are issuable under the 2003 Plan. As of August 31, 2005, no options granted under the 2003 Plan have been exercised.

1996 Stock Option Plan

In 1996, we adopted our 1996 Stock Option Plan (1996 Plan). The 1996 Plan permitted the granting of awards to our officers, key employees, directors and collaborating scientists in the form of incentive or nonqualified stock options. Stock options granted under the 1996 Plan may be "incentive stock options" meeting the requirements of Section 422 of the Code or nonqualified stock options which do not meet the requirements of Section 422. Since the adoption of the 2003 Plan, we have not granted any stock options under the 1996 Plan. As of June 30, 2005, options to purchase 260,178 shares of our common stock are outstanding under the 1996 Plan. No further options or other equity-based awards are issuable under the 1996 Plan. As of August 31, 2005, no options granted under the 1996 Plan have been exercised.

Employment Agreement

Employment Agreement with Joseph V. Gulfo, M.D.

On January 5, 2004, we entered into an employment agreement with Dr. Joseph V. Gulfo, our President and Chief Executive Officer. Pursuant to the agreement, Dr. Gulfo is required to devote substantially all of his business time, attention and efforts to the performance of his duties under the agreement. The initial term of the employment agreement extends until December 31, 2005 and will automatically renew for successive twelve-month (12) terms unless

either party sends a written notice of termination within 90 days of the expiration of the initial term or renewal term, as the case may be.

The employment agreement provides Dr. Gulfo with an annual base salary of $175,000 subject to periodic review by our board of directors. Our board of directors has determined that Dr. Gulfo was entitled to a review and salary increase in an amount to be agreed by Dr. Gulfo and the Company as a result of the equity financing consummated in October 2004, but to date our board of directors has not conducted a review or granted a salary increase. Dr. Gulfo is also entitled to receive yearly bonuses at the discretion of our board of directors. The target for such bonuses is 50% of Dr. Gulfo's then current base salary.

In addition, Dr. Gulfo is entitled to be reimbursed for certain travel expenses up to $1,100 per month, $2,000 per month for lodging expenses and for certain communication expenses, including cellular phone service and broadband internet service.

If Dr. Gulfo's employment is terminated by us without cause or Dr. Gulfo resigns for good reason, then Dr. Gulfo would be entitled to receive severance pay equal to 15 months of his then current base salary and, if Dr. Gulfo is then covered by health insurance provided by us, the cost to Dr. Gulfo of COBRA coverage for 15 months. If we elect not to renew Dr. Gulfo's employment agreement, Dr. Gulfo is entitled to an amount equal to his then current base salary for nine months and, if Dr. Gulfo is covered by our health insurance policy at such time, the cost of COBRA for nine months (subject to reduction to the extent Dr. Gulfo received comparable benefits from a subsequent employer during such nine month period).

Dr. Gulfo is subject to a non-compete covenant upon termination of his employment by us or him. The term of Dr. Gulfo's non-compete covenant is one (1) year, which can be extended to two (2) years in the event we elect to pay him additional severance equal to twelve (12) months of his base salary at the time of termination and his most recent bonus (if any).

The employment agreement provides for three separate grants of stock options. As of May 15, 2005, the first two stock option grants for the purchase of a total of 81,753 shares of our common stock at an exercise price of $0.46 per share have fully vested. The number of shares of our common stock subject to the third stock option can only be calculated at the time of PMA approval of MelaFind®. The number of shares purchasable under this option at an exercise price of $0.46 per share is equal to that number of shares of our common stock equal to four percent of our fully-diluted capital stock at the time of PMA approval of MelaFind® minus the number of shares of common stock underlying options granted to Dr. Gulfo under the employment agreement, which is 81,753. Assuming that 10,513,164 shares are outstanding as of the completion of this offering and remain the total number of shares outstanding on the date we receive PMA approval of MelaFind®(assuming in both cases the exercise of all outstanding options and warrants and the conversion of all convertible securities), the number of shares subject to this option would be 387,366. This third stock option grant vests 50% at the time of PMA approval of MelaFind®, and the remaining 50% vests in four equal installments over the one year period following such PMA approval of MelaFind®.

Consulting Agreements

Consulting Agreement with Breaux Castleman

In June 2003, we entered into a consulting agreement with Breaux Castleman for consulting services related to FDA approval of MelaFind®, administrative matters, financial reporting, and our business and financial strategy. Under this agreement, Mr. Castleman receives compensation for each month of services rendered. During 2003 Mr. Castleman was paid at the rate of $8,000 for each month of services rendered and thereafter from 2004 onward he has been paid at the rate of $2,000 for each month of services rendered. We made payments pursuant to this consulting agreement of $48,000 in 2003, $22,000 in 2004, and $12,000 in 2005. These payments did not exceed $60,000 in any twelve-month period since June 2003. In connection with our consulting agreement with Mr. Castleman, we granted Mr. Castleman a restricted stock award of 75,000 shares of our common stock under our 2003 Plan for an aggregate purchase price of $34,500. Mr. Castleman issued an interest-bearing promissory note in the principal amount of $34,500 as payment for these shares. During the second quarter of 2005, this note was repaid in full. Our consulting agreement with Mr. Castleman is terminable by either party on 30 days' written notice.

Consulting Agreement with Marek Elbaum, Ph.D.

Pursuant to a consulting agreement effective as of May 31, 2005, we retained Marek Elbaum, Ph.D., our founder and former Chief Science and Technology Officer, as our Chief Scientist to provide services relating to the integration of our product development, mentoring and advising our staff scientists, providing new product vision, supporting of our research and development and providing such other services as assigned to him by our Chief Executive Officer. Pursuant to the consulting agreement, Dr. Elbaum will provide us with a majority of his business time in consideration of a monthly fee of approximately $14,500. The term of such agreement extends for a period of two years and is automatically renewable for an additional one year period unless either Dr. Elbaum or we decide to not so renew. In the event of a non-renewal, and in the event that Dr. Elbaum's services terminate as a result of his death or disability, we will pay to Dr. Elbaum a termination fee of $100,000. In addition, upon termination of the consulting agreement for any reason other than a termination by us for cause, we will pay to Dr. Elbaum for 18 months an amount equal to what Dr. Elbaum would have had to pay to extend his insurance coverage under COBRA. Dr. Elbaum is subject to a non-compete covenant during the term of the consulting agreement and for a period of two years after the term of the consulting agreement. We have also agreed that all stock options previously granted to Dr. Elbaum will continue to vest in accordance with their original terms.

Consulting Agreement with Robert Friedman, M.D.

Pursuant to a consulting agreement effective as of June 1, 2005, we have retained the services of Robert Friedman, M.D. for an initial term of one year as a consultant, medical advisor to our board of directors, and as a liaison between our board of directors and our Scientific and Medical Advisory Committee, and in connection with the clinical testing of MelaFind®. In consideration of rendering of these services, Dr. Friedman will be paid at a rate of $5,000 per day (assuming an eight-hour day) for up to 30 days of service. The consulting agreement is automatically renewed for successive one-year terms unless either party terminates the agreement at least 30 days prior to the expiration of the agreement.

Consulting Agreement with Gerald Wagner, Ph.D.

Pursuant to a consulting agreement dated as of June 1, 2005 with Gerald Wagner Consulting LLC (GWC), a company owned and operated by Dr. Gerald Wagner, GWC has agreed to direct our MelaFind® product development efforts and oversee the manufacturing process for a period that began June 1, 2005 and ends three months following the initiation of our pivotal clinical trial of MelaFind®. The consulting agreement provides for a flat fee of $150,000, payable ratably over the course of the term, and the grant to Dr. Wagner immediately after completion of this offering of a non-qualified stock option to purchase up to 50,000 shares of our common stock at the public offering price per share.

Limitation of Liability and Indemnification of Directors and Officers

Our fourth amended and restated certificate of incorporation and third amended and restated bylaws provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. Our fourth amended and restated certificate of incorporation and third amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in such capacity, regardless of whether the bylaws would permit indemnification. We maintain directors' and officers' liability insurance. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

Related party transactions

We also describe below certain other transactions with our directors, executive officers and stockholders.

Common Stock

In June 2003, we sold 75,000 shares of our common stock at a price of $0.46 per share to Dr. Robert Friedman, a former member of our board of directors, and 75,000 shares of our common stock at a price of $0.46 per share to Breaux Castleman, a member of our board of directors, and the chairman of our board. In May 2004, we issued 125,000 shares of our common stock at a per share purchase price of $0.46 to investors who loaned an aggregate of $1,000,000 to the Company, which loans were evidenced by convertible promissory notes, all of which converted into shares of our Series C preferred stock on October 26, 2004.

Certain of our directors, officers, existing shareholders, their affiliates, family members and family trusts (including, but not limited to Dan W. Lufkin, Joseph V. Gulfo, M.D., Gerald Wagner, Ph.D., their affiliates, family members and family trusts) may purchase up to 405,000 shares of our common stock in this offering.

Preferred Stock

All share numbers and share prices presented below for our preferred stock and Series C preferred stock warrants do not reflect the 1-for-2 reverse stock split which has occurred with respect to our common stock. The shares of our common stock into which our preferred stock will convert and the share prices reflect the reverse stock split.

In 1998, we issued 198,000 shares of our Series A preferred stock at a per share purchase price of $5.00 to 22 accredited investors for an aggregate consideration of $990,000. All shares of Series A preferred stock will convert into an aggregate of 115,201 shares of our common stock upon completion of this offering.

In 2000 and 2001, we issued an aggregate of 947,986 shares of our Series B preferred stock in three transactions at per share purchase prices of $5.1282 and $6.50 to 149 accredited investors for an aggregate consideration of $5,894,409. The rights of the holders of Series B preferred stock were identical except for the purchase prices paid for such stock. The purchasers of our Series B preferred stock included Arcadian Venture Partners L.P., a venture fund with which George C. Chryssis, a member of our board of directors, is affiliated, and Double D Venture Fund, LLC, a venture fund with which Sidney Braginsky, a member of our board of directors, is affiliated.

On June 20, 2003, we issued an aggregate of 45,000 shares of our Series B preferred stock to the original Series B preferred stock investors in consideration of certain amendments to their investment agreements, bringing the total number of shares of our Series B preferred stock outstanding to 992,986. All shares of our Series B preferred stock will convert into an aggregate of 575,532 shares of our common stock upon completion of this offering.

From June 2003 to October 2004, we sold an aggregate of 5,414,779 shares of our Series C preferred stock (together with warrants to purchase an aggregate of 2,610,643 shares of our common stock, all of which warrants have been converted into an aggregate of 1,305,321 shares of our common stock pursuant to the warrant exchange described below under “Warrants to Purchase Common Stock”) to 73 accredited investors for an aggregate consideration of $12,191,480. These investors included: Breaux Castleman, a member of our board of directors and chairman of our board; Dr. Robert Friedman, a member of our scientific and medical advisory committee and former member of our board of directors; Double D Venture Fund, LLC, a venture fund with which Sidney Braginsky, a member of our board of directors, is affiliated; and Dan W. Lufkin, a member of our board of directors. All shares of our Series C preferred stock will convert into an aggregate of 2,707,372 shares of our common stock upon completion of this offering.

Warrants to Purchase Preferred Stock

In June 2003, we issued a warrant to purchase up to 24,890 shares of our Series C preferred stock at an exercise price of $2.26 per share to Koji Miyazaki, one of our Series C preferred stock investors.

In February 2004, we issued a warrant to purchase up to 121,681 shares of our Series C preferred stock with an exercise price of $2.26 per share to Health Partners I, LLC (HP I). In November 2004, HP I was dissolved and this

warrant, together with all shares of our Series C preferred stock and warrants to purchase our common stock previously issued to HP I, were distributed to HP I's members, which included: Dr. Robert Friedman, a member of our scientific and medical advisory committee and a former member of our board of directors; Breaux Castleman, a member of our board of directors and chairman of our board; and Dan W. Lufkin, a member of our board of directors. Assuming conversion of our preferred stock prior to completion of this offering, these warrants and the warrant issued to Mr. Miyazaki will be exercisable for an aggregate of 73,280 shares of our common stock at an exercise price of $4.52 per share.

Warrants to Purchase Common Stock

We have consummated an exchange of warrants to purchase our common stock for shares of our common stock under a plan of recapitalization adopted by our board of directors. During the period from June 2003 through October 2004, we issued warrants to purchase an aggregate of up to 2,610,643 shares of our common stock to certain holders of our Series C preferred stock. All of these warrants had an exercise price of $13.00 per share. In June 2003, we also issued a warrant to Dr. Marek Elbaum, our former Chief Science and Technology Officer, to purchase up to 25,000 shares of our common stock at per share exercise price of $13.00. In December 2004, we issued a warrant to Allen & Company LLC to purchase up to 75,000 shares of our common stock at an exercise price of $7.00 per share (Allen & Company Warrant) in consideration of Allen & Company LLC's agreement to provide certain advisory services to us. Warrants to purchase a total of 2,610,643 shares of our common stock have been exchanged for a total of 1,305,321 shares of our common stock based on an exchange ratio of one share of our common stock for every two shares of our common stock purchasable under the warrants (Warrant Exchange).

The only warrants that remain outstanding are the Allen & Company Warrant, the Underwriters' Warrant (see "Underwriting") and warrants to purchase an aggregate of 146,571 shares of our Series C preferred stock, which assuming conversion of such Series C preferred stock will be exercisable for an aggregate of 73,280 shares of our common stock.

Options

From inception to August 31, 2005, we have granted an aggregate of 525,989 options to our current directors and named executive officers, with exercise prices ranging from $0.46 to $10.00 per share.

Voting Agreement

We entered into a voting agreement with certain holders of our common stock and preferred stock, which fixes the size of our board of directors at nine and entitles the holders of a majority of our common stock to designate two directors, the holders of a majority of our Series B preferred stock to designate one director and the holders of a majority of our Series C preferred stock to designate four directors. Currently, Joseph V. Gulfo, M.D. is the sole designee of the holders of our common stock, George C. Chryssis is the designee of the holders of our Series B preferred stock, and Breaux Castleman and Dan W. Lufkin are the sole designees of the holders of our Series C preferred stock. Upon the closing of this offering, the voting agreement will be terminated and none of our stockholders will have any special rights regarding board representation.

Principal stockholders

The following tables set forth as of August 31, 2005, and as adjusted to reflect the sale of the shares offered hereby, certain information regarding beneficial ownership of our common stock by:

- each person or group of affiliated persons known to us to beneficially own more than 5% of our common stock;
- each named executive officer;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage of ownership indicated in the following table is based on 6,513,164 shares of common stock outstanding on August 31, 2005 and 10,513,164 shares of common stock outstanding immediately following the completion of this offering, each of which assumes the conversion of all outstanding shares of our preferred stock and consummation of the Warrant Exchange. The table assumes no exercise of the underwriters' over-allotment option.

Information with respect to beneficial ownership has been furnished by each director, officer, beneficial owner of more than 5% of our common stock or selling stockholder and is determined in accordance with the rules of the SEC. Except as indicated by footnote and subject to community property laws where applicable, to our knowledge, the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. In computing the number of shares beneficially owned by a person and the percentage of ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or will become exercisable within 60 days after August 31, 2005 are deemed outstanding, while such shares are not deemed outstanding for purposes of computing percentage ownership of any other person. The number of shares of common stock shown in the table below does not include any shares of our common stock that may be purchased by such persons in this offering.

	Number of shares of common stock beneficially owned		Percentage of shares beneficially owned	
Name of beneficial owner	**Shares**	**Options and warrants exercisable within 60 days**	**Before the offering**	**After the offering**
Named Executive Officers				
Joseph V. Gulfo, M.D.	—	81,753	1.2%	*
Marek Elbaum, Ph.D.(1)	462,500	14,070	7.3	4.5%
Karen Krumeich	—	60,000	*	*
William R. Bronner	4,850	70,285	1.1	*
Jon I. Klippel	—	45,000	*	*
Directors				
Breaux Castleman	91,570	6,168	1.5	*
Sidney Braginsky(2)	51,500	5,000	*	*
George C. Chryssis(3)	94,717	12,500	1.6	1.0
Dan W. Lufkin(4)	356,231	29,187	5.9	3.7
Gerald Wagner, Ph.D.	—	—	—	—
All directors and named executive officers as a group (all 10 persons)	1,061,368	323,963	20.3%	12.8%
Holders of more than 5%				
Patricia and Stanley Brilliant(5)	349,532	2,342	5.4	3.4
S. Donald Sussman(6)	917,767	11,693	14.2	8.8
Eric Dobkin(7)	351,523	7,015	5.5	3.4

* Less than one percent.

Principal stockholders

(1) Marek Elbaum, Ph.D. resigned as a director and our Chief Science and Technology Officer effective as of May 31, 2005.

(2) Includes 51,500 shares of common stock held by Double D Venture Fund, LLC, an investment fund with which Mr. Braginsky is affiliated. Mr. Braginsky expressly disclaims ownership of these shares except to the extent of his pecuniary interest in Double D Venture Fund, LLC.

(3) Includes 94,717 shares of common stock held by Arcadian Venture Partners, L.P., an investment fund with which Mr. Chryssis is affiliated. Mr. Chryssis expressly disclaims ownership of these shares except to the extent of his pecuniary interest in Arcadian Venture Partners, L.P.

(4) Includes 140,570 shares of common stock held by trusts the beneficiaries of which are family members of Mr. Lufkin and 5,840 shares of common stock issuable upon exercise of Series C preferred stock warrants. Mr. Lufkin expressly disclaims ownership of the shares held by these trusts.

(5) Patricia and Stanley Brilliant are husband and wife. Their business address is: 180 East End Avenue, Apt. 4A, New York, NY 10128.

(6) The business address of S. Donald Sussman is: 2 American Lane, Greenwich, CT 06836.

(7) The business address of Eric Dobkin is: 160 Old Church Lane, Pound Ridge, NY 10576.

Description of capital stock

The following information describes our common stock and preferred stock and provisions of our fourth amended and restated certificate of incorporation and our third amended and restated bylaws as in effect upon the closing of this offering. This description is only a summary. You should also refer to the fourth restated certificate of incorporation and third amended and restated bylaws which will be filed with the SEC as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the receipt of the requisite board and stockholder approvals and upon the closing of this offering in accordance with the terms of the fourth amended and restated certificate of incorporation.

Upon completion of this offering, and after giving effect to the conversion of all outstanding convertible preferred stock into common stock and the amendment of our fourth amended and restated certificate of incorporation, our authorized capital stock will consist of 30,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.10 par value per share. As of August 31, 2005, there were 6,513,164 shares of our common stock outstanding held of record by 242 stockholders.

Common Stock

Subject to preferences that may be applicable to any shares of preferred stock outstanding at the time, the holders of common stock are entitled to the following:

Dividends. The holders of outstanding shares of our common stock are entitled to receive dividends out of assets legally available for the payment of dividends at the times and in the amounts as our board of directors from time to time may determine, subject to any preferential dividend rights of any holder of outstanding shares of our preferred stock.

Voting. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders, including the election of directors. We have not provided for cumulative voting for the election of directors in our fourth restated certificate of incorporation. This means that the holders of a majority of the shares voted can elect all of the directors then standing for election.

Preemptive rights, conversion and redemption. Our common stock is not entitled to preemptive rights and is not subject to conversion or redemption.

Liquidation, dissolution and winding-up. Upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any preferred stock.

Each outstanding share of common stock is, and all shares of common stock to be issued in this offering when they are paid for, will be duly and validly issued, fully paid and non-assessable.

Options

As of August 31, 2005, options to purchase a total of 899,875 shares of common stock were outstanding. All options issued under the 2003 Plan or issuable under the 2005 Plan are subject to 180-day lock-up provisions under the terms of the 2003 Plan and the 2005 Plan, respectively. Options to purchase a total of 1,000,000 shares of common stock remain available for grant under the 2005 Plan. Following this offering, no options to purchase, or other equity-based awards with respect to shares of our common stock, will be available under the 2003 Plan or the 1996 Plan.

Preferred Stock

Upon the closing of this offering, all outstanding shares of our preferred stock will convert into an aggregate of 3,398,105 shares of common stock.

Following the offering, our board of directors will be authorized, subject to the limits imposed by the Delaware General Corporation Law, to issue 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any of its qualifications, limitations and restrictions. Our board of directors can also increase

or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that adversely affect the voting power or other rights of our common stockholders. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, financings and other corporate purposes, could have the effect of delaying, deferring or preventing a change in control and may cause the market price of our common stock to decline or impair the voting and other rights of the holders of our common stock. We have no current plans to issue shares of preferred stock.

Warrants

See "Related party transactions — Warrants to Purchase Preferred Stock" and "Related party transactions — Warrants to Purchase Common Stock."

Registration Rights

Under a second amended and restated investors' rights agreement, following this offering, the holders of 5,090,001 shares of common stock (including shares of our common stock purchasable pursuant to warrants to purchase our common stock) have the right to require us to register their shares with the SEC so that those shares may be publicly resold or to include their shares in any registration statement we file with the SEC.

Demand Rights

At any time after the earlier of October 26, 2009 or the date which is one year after the effective date of this offering, if the holders of more than 20% of the outstanding shares of common stock issued or issuable upon conversion of our existing Series B preferred stock or Series C preferred stock or upon exercise of warrants to purchase our common stock held by holders of our existing Series B preferred stock or Series C preferred stock, request that we file a registration statement with the SEC having an aggregate offering price to the public (after deduction of underwriter's discounts and expenses) of not less than $2,000,000, we are obligated to use our commercially reasonable efforts to cause such shares to be registered and to include in such registration, if requested, additional shares of our common stock requested to be included by holders of registration rights who deliver a written notice to us within 20 days of our receipt of notice from the initiating holders. We are only required to effect two such registrations, and we are not required to effect any such registration during period commencing 90 days before a company initiated registration and ending 90 days after a company initiated registration. Our board of directors has the right to defer for not more than 90 days and not more than twice in any 12-month period any such registration if in its good faith judgment such registration would be detrimental to us and not in our best interest.

If we are eligible to file a registration statement on Form S-3, holders of shares having registration rights have the right to demand on or prior to the fifth anniversary of the effective date of this offering that we file a registration statement on Form S-3. We are only required to effect two such registrations in any 12-month period, and we are not required to effect any such registration during period commencing 90 days before a company-initiated registration and ending 90 days after a company-initiated registration.

Piggy-Back Registration Rights

The holders of shares having registration rights are entitled to unlimited "piggy-back" registration rights on all registrations of our stock other than a registration relating solely to employee benefit plans, a registration on Form S-4 or any other form that does not permit secondary sales or a registration pursuant to the demand rights described above. Pursuant to the lock-up agreements we expect to enter into with our directors, officers and certain stockholders, any such person holding "piggy-back" registration rights will waive such rights with respect to this offering.

Limitations on Registration Rights

We and the underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement. The underwriters have excluded any sales by existing investors in this offering.

Expenses of Registration

We shall bear all registration expenses, exclusive of underwriting discounts, selling commissions, stock transfer taxes and fees and disbursements of counsel for the holders of registration rights (other than customary fees of one counsel in the case of a demand registration), of all demand and piggy-back registrations.

Delaware Anti-Takeover Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or Delaware law, regulating corporate takeovers. In general, these provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- the transaction is approved by the board of directors before the date the interested stockholder attained that status;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or
- on or after the date the business combination is approved by the board of directors and authorized at a meeting of stockholders, by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

A Delaware corporation may opt out of this provision either with an express provision in its original certificate of incorporation or in an amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

Provisions of our Certificate of Incorporation and Bylaws and Certain Regulatory Requirements That May Have an Anti-Takeover Effect or Entrench Current Management

Our fourth amended and restated certificate of incorporation and third amended and restated bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and the policies formulated by our board of directors. These provisions are also expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. These provisions, as well as certain provisions of contracts to which we are a party,

may discourage or hinder attempts to acquire us or remove incumbent directors or management even if some, or a majority, of our stockholders believe that such action is in their best interest.

Certificate of Incorporation and Bylaws.

The provisions in our fourth amended and restated certificate of incorporation and third amended and restated bylaws with the intent described above include:

- **Vacancies Filled by the Board.** Vacancies on our board of directors may be filled by a majority of the remaining directors (even if they constitute less than a quorum), or by a sole remaining director.
- **Removal of Directors.** None of our directors may be removed other than for cause.
- **Stockholder Meetings.** Only our board of directors, the chairman of our board of directors or our chief executive officer may call special meetings of stockholders. Stockholders cannot call special meetings of stockholders.
- **No Action by Written Consent.** Stockholders may take action only at an annual or special meeting of stockholders. Stockholders may not act by written consent.
- **Requirements for Advance Notification of Stockholder Proposals and Director Nominations**. Stockholders must comply with advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors. In general, these provisions will provide that notice of intent to nominate a director or raise matters at such meetings must be received in writing by us not less than 90 nor more than 120 days prior to the anniversary of the date of the proxy statement for the previous year's annual meeting of stockholders, and must contain certain information concerning the person to be nominated or the matters to be brought before the meeting and concerning the stockholder submitting the proposal.
- **No Cumulative Voting.** There is no cumulative voting in the election of directors.
- **"Blank Check" Preferred Stock**. We will be authorized to issue, without any further vote or action by the stockholders, up to 10,000,000 shares of preferred stock in one or more classes or series and, with respect to each such class or series, to fix the number of shares constituting the class or series and the designation of the class or series, the voting powers (if any) of the shares of the class or series, and the preferences and relative, participating, optional and other special rights, if any, and any qualifications, limitations or restrictions, of the shares of such class or series.
- **Regulatory Approval.** We are also required to obtain the approval of certain regulatory agencies, such as the NASD, for certain transactions that could result in a change of control. See "Business — Regulation."

Transfer Agent and Register

The transfer agent and registrar for the common stock is the American Stock Transfer and Trust Company.

Listing

Our common stock has been approved for quotation, subject to official notice of issuance, on the NASDAQ Capital Market under the symbol "MELA." We have not applied to list our common stock on any other exchange or quotation system.

Shares eligible for future sale

Prior to this offering, there has been no market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding options and warrants or in the public market after this offering, or the anticipation of those sales, could adversely affect the price of our common stock from time to time and could impair our ability to raise capital through sales of our equity securities. Upon completion of this offering, we will have outstanding an aggregate of 10,513,164 shares of common stock, after giving effect to the issuance of 4,000,000 shares of common stock in this offering and the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,398,105 shares of our common stock.

Sales of Restricted Shares

Of the shares to be outstanding after the completion of this offering, the 4,000,000 shares sold in this offering will be freely tradable without restriction under the Securities Act of 1933, as amended (Securities Act) unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Of the remaining 6,513,164 shares of common stock, 598,868 are held by current "affiliates" and 1,034,045 are held by former "affiliates" (that is, persons whose affiliate status terminated less than 90 days before the date of this prospectus). The shares of common stock held by affiliates and all other shares of common stock other than those sold in this offering are "restricted securities" within the meaning of Rule 144. All of the shares of common stock held by affiliates will be subject to the 270-day lock-up period described below. After the 270-day lock-up period, these restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144, 144(k) or 701 promulgated under the Securities Act, which are summarized below. Sales of the restricted securities in the public market, or the availability of such shares for sale, could adversely affect the market price of our common stock.

Our directors, officers and certain significant stockholders have entered into lock-up agreements in connection with the offering generally providing that they will not offer, sell, contract to sell or grant any option to purchase or otherwise dispose of our common stock or any securities exercisable for or convertible into our common stock owned by them for a period of 270 days after the date of this prospectus without the prior written consent of the underwriters, which consent may be withheld in their sole discretion. Taking into account the lock-up agreements, and assuming the underwriters do not release any stockholders from these agreements, we estimate that the number of restricted shares that will be available for sale in the public market under the provisions of Rule 144 and Rule 144(k) will be approximately as follows:

- beginning on the effective date of this prospectus, in addition to the shares sold in the offering, approximately 1,229,577 of our restricted shares will be eligible for sale under Rule 144, of which approximately 408,402 shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144 and approximately 821,175 shares will be eligible for sale as unrestricted shares under Rule 144(k);
- beginning 270 days after the effective date of this prospectus, approximately 6,347,015 of our restricted shares will be eligible for sale under Rule 144 (which includes the 1,229,577 restricted shares referred to above), of which approximately 3,226,819 shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144 and approximately 3,120,196 shares will be eligible for sale as unrestricted shares under Rule 144(k); and
- beginning October 27, 2006, approximately an additional 166,149 of restricted shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144.

In general, under Rule 144 as currently in effect, after the expiration of the lock-up agreements, a person who has beneficially owned restricted securities for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- one percent of the number of shares of common stock then outstanding, which will equal approximately 95,136 shares immediately after the offering; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 are also subject to requirements with respect to manner of sale, notice and the availability of current public information about us. However, under Rule 144(k), generally, a person who is not deemed to have been our affiliate at any time during the three months preceding a sale and who has beneficially owned the shares proposed to be sold for at least two years, is entitled to sell such shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, any of our employees, directors or consultants who purchased shares of our common stock from us in connection with our stock option plans before the effective date of the registration statement of which this prospectus is a part, or who hold stock options as of that date, may rely on the resale provisions of Rule 701. Under Rule 701, these persons who are not our affiliates may generally sell their eligible securities, commencing 90 days after the effective date of the registration statement in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period and volume limitations contained in Rule 144. Rule 152 under the Securities Act provides a safe harbor for transactions not involving any public offering even if the issuer subsequently files a registration statement. Also, Rule 701 states that offers and sales exempt under Rule 701 are deemed to be part of a single, discrete offering and are not subject to integration with other offers or sales (whether registered or not). We therefore believe that the issuance of common stock upon the exercise of options by our employees, directors or consultants should not be integrated with the issuance of common stock in this offering.

Subject to the 270-day lock-up period described above, as of the date 90 days after the effective date of this offering, holders of vested options exercisable for approximately 573,550 shares of our common stock will be eligible to exercise their options and to sell their shares in accordance with Rule 701.

Stock Options

We intend to file a registration statement under the Securities Act covering the shares of common stock reserved for issuance upon exercise of outstanding options under our 2005 Plan, our 2003 Plan and our 1996 Plan. The registration statement is expected to be filed 270 days after the closing of this offering and become effective as soon as practicable after filing. Accordingly, shares registered under the registration statement will be available for sale in the open market after the effective date of the registration statement subject to manner of sale, public information, volume limitation and notice provisions of Rule 144 applicable to our affiliates, and any limitations on sale under the applicable option plan and the lock-up agreements described above. See “Risk factors — If there are substantial sales of our common stock, our stock price could decline.”

Material US federal income and estate tax considerations for non-US holders

The following is a general discussion of the material US federal income and estate tax consequences of the ownership and disposition of our common stock by a non-US holder that purchases shares pursuant to this offer. As used in this discussion, the term non-US holder means a beneficial owner of our common stock that is not, for US federal income tax purposes:

- an individual who is a citizen or resident of the US;
- a corporation or partnership (including any entity treated as a corporation or partnership for US federal income tax purposes) created or organized in or under the laws of the US or any State thereof or the District of Columbia, other than a partnership treated as foreign under US Treasury regulations;
- an estate whose income is includible in gross income for US federal income tax purposes regardless of its source; or
- a trust (1) if a US court is able to exercise primary supervision over the administration of the trust and one or more US persons have authority to control all substantial decisions of the trust, or (2) that has a valid election in effect under applicable Treasury regulations to be treated as a US person.

This discussion does not consider:

- US federal gift tax consequences, US state or local or non-US tax consequences;
- specific facts and circumstances that may be relevant to a particular non-US holder's tax position, including, if the non-US holder is a partnership or trust that the US tax consequences of holding and disposing of our common stock may be affected by certain determinations made at the partner or beneficiary level;
- the tax consequences for the stockholders, partners or beneficiaries of a non-US holder;
- special tax rules that may apply to particular non-US holders, such as financial institutions, insurance companies, tax-exempt organizations, hybrid entities, US expatriates, broker-dealers, and traders in securities; or
- special tax rules that may apply to a non-US holder that holds our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment.

The following discussion is based on provisions of the Code, applicable US Treasury regulations and administrative and judicial interpretations, all as in effect on the date of this prospectus, and all of which are subject to change, retroactively or prospectively. The following summary assumes that a non-US holder holds our common stock as a "capital asset" within the meaning of section 1221 of the Code (generally, property held for investment). Each non-US holder should consult a tax advisor regarding the US federal, state, local and non-US income and other tax consequences of acquiring, holding and disposing of shares of our common stock.

Dividends

We do not plan to pay any dividends on our common stock for the foreseeable future. However, in the event that we pay dividends on our common stock, we will have to withhold a US federal withholding tax at a rate of 30%, or a lower rate under an applicable income tax treaty, from the gross amount of dividends paid to a non-US holder.

Dividends that are effectively connected with a non-US holder's conduct of a trade or business in the US or, if an income tax treaty applies, attributable to a permanent establishment in the US (effectively connected income or ECI), are taxed on a net income basis at the regular graduated rates and in the manner applicable to US persons. In that case, we will not have to withhold US federal withholding tax if the non-US holder complies with applicable certification and disclosure requirements. In addition to the US tax on ECI, in the case of a holder that is a foreign corporation and

has ECI, a branch profits tax may be imposed at a 30% rate, or a lower rate under an applicable income tax treaty, on the dividend equivalent amount.

In order to claim the benefit of an income tax treaty or claim exemption from withholding because the income is effectively connected with the conduct of a trade or business in the US, the non-US holder must provide a properly executed Form W-8BEN, for treaty benefits, or W-8ECI, for effectively connected income, prior to the payment of dividends. These forms must be periodically updated. Non-US holders should consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty and their ability to claim exemption from withholding because the income is effectively connected with the conduct of a trade or business in the US, and related certification requirements.

A non-US holder that is eligible for a reduced rate of US federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the US Internal Revenue Service (IRS) in a timely manner.

Gain on Disposition of Common Stock

A non-US holder generally will not be taxed on gain recognized on a disposition of our common stock unless:

- the gain is effectively connected with a non-US holder's conduct of a trade or business in the US or, alternatively, if an income tax treaty applies, is attributable to a permanent establishment maintained by the non-US holder in the US; in these cases, the gain will be taxed on a net income basis at the regular graduated rates and in the manner applicable to US persons, unless an applicable treaty provides otherwise, and, if the non-US holder is a foreign corporation, the branch profits tax described above may also apply;
- the non-US holder is an individual who holds our common stock as a capital asset, is present in the US for 183 days or more in the taxable year of the disposition and meets other requirements; in this case, the non-US holder will be subject to a 30% tax on the gain derived from the disposition; or
- we are or have been a US real property holding corporation (USRPHC) for US federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-US holder held our common stock; in this case, the non-US holder may be subject to US federal income tax on its net gain derived from the disposition of our common stock at regular graduated rates. Generally, a corporation is a USRPHC if the fair market value of its US real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. If we are, or were to become, a USRPHC, gain realized upon disposition of our common stock by a non-US holder that did not directly or indirectly own more than 5% of our common stock during the shorter of the five-year period ending on the date of disposition or the period that the non-US holder held our common stock generally would not be subject to US federal income tax, provided that our common stock is "regularly traded on an established securities market" within the meaning of Section 897(c)(3) of the Code. We believe that we are not currently, and we do not anticipate becoming in the future, a USRPHC.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-US holder at the time of death, unless an applicable estate tax or other treaty provides otherwise, will be included in the individual's gross estate for US federal estate tax purposes, and therefore may be subject to US federal estate tax.

Information Reporting and Backup Withholding Tax

We must report annually to the IRS and to each non-US holder the amount of dividends paid to that holder and the tax withheld from those dividends. These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable income tax treaty. Copies of the information returns reporting those dividends and

withholding may also be made available to the tax authorities in the country in which the non-US holder is a resident under the provisions of an applicable income tax treaty or agreement.

Under some circumstances, US Treasury regulations require additional information reporting and backup withholding (currently at a rate of 28%) on some payments on our common stock. The gross amount of dividends paid to a non-US holder that fails to certify its non-US holder status in accordance with applicable US Treasury regulations generally will be reduced by backup withholding at the applicable rate.

The payment of the proceeds of the disposition of our common stock by a non-US holder to or through the US office of any broker generally will be reported to the IRS and reduced by backup withholding unless the non-US holder either certifies its status as a non-US holder under penalties of perjury or otherwise establishes an exemption. The payment of the proceeds of the disposition of our common stock by a non-US holder to or through a non-US office of a non-US broker generally will not be reduced by backup withholding or reported to the IRS unless the non-US broker has certain enumerated connections with the US. In general, the payment of proceeds from the disposition of our common stock by or through a non-US office of a broker that is a US person or that has certain enumerated connections with the US will be reported to the IRS and may, in limited circumstances, be reduced by backup withholding, unless the broker receives a statement from the non-US holder, signed under penalty of perjury, certifying its non-US status or the broker has documentary evidence in its files that the holder is a non-US holder.

Non-US holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-US holder will be refunded, or credited against the holder’s US federal income tax liability, if any, provided that the required information or appropriate claim for refund is furnished to the IRS in a timely manner.

Underwriting

ThinkEquity Partners LLC is acting as sole bookrunner of the offering and, together with Stanford Group Company, are acting as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has agreed to purchase, and we have agreed to sell to that underwriter, the number of the shares set forth opposite the underwriter's name.

Underwriters	Number of shares
ThinkEquity Partners LLC	2,000,000
Stanford Group Company	2,000,000
Total	4,000,000

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to the approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of the shares (other than those covered by the over-allotment option described below) if they purchase any of the shares.

The underwriters propose to offer some of the shares directly to the public at the public offering price set forth on the cover page of this prospectus and some of the shares to dealers at the public offering price less a concession not to exceed $.21 per share. The underwriters may allow, and dealers may reallow, a concession not to exceed $.10 per share on sales to other dealers. If all of the shares are not sold at the initial offering price, the representatives may change the public offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to confirm any sales to any accounts over which they exercise discretionary authority.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 600,000 additional shares of our common stock at the public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional shares approximately proportionate to that underwriter's initial purchase commitment.

Except as noted below, our directors, executive officers and certain significant stockholders have agreed with ThinkEquity Partners LLC that for a period of 270 days following the date of this prospectus, they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any of our shares of common stock or any securities convertible into or exchangeable for shares of common stock. ThinkEquity Partners LLC may, in its sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement. We have entered into an agreement with the representatives, stating that we will not issue additional shares (with the exception of shares issued pursuant to the over-allotment option) of our common stock prior to the end of the 270 day period following the date of this prospectus, other than with respect to our issuing shares pursuant to employee benefit plans, qualified option plans or other employee compensation plans already in existence, or pursuant to currently outstanding options, warrants or other rights to acquire shares of our common stock. There are no agreements between the representatives and any of our directors, executive officers or principal stockholder releasing them from these lock-up agreements, or with us pertaining to our issuance of additional shares, prior to the expiration of the 270 day period.

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for the shares was determined by negotiations between us, and the representatives. Among the factors considered in determining the initial public offering price were our record of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management, and currently prevailing general conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our company. We cannot assure you, however, that the prices at which the shares will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our common stock will develop and continue after this offering.

Underwriting

Our common stock has been approved for quotation, subject to official notice of issuance, on the NASDAQ Capital Market under the symbol “MELA.”

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase additional shares of common stock.

	No exercise	Full exercise
Per share	$ .35	$ .35
Total	$ 1,400,000	$ 1,610,000

In connection with the offering, ThinkEquity Partners LLC, on behalf of the underwriters, may purchase and sell shares of common stock in the open market. These transactions may include a short sales, syndicate covering transactions and stabilizing transactions. Short sales involve syndicate sales of common stock in excess of the number of shares to be purchased by the underwriters in the offering, which create a syndicate short position. “Covered” short sales are sales of shares made in an amount up to the number of shares represented by the underwriters’ over-allotment option. In determining the source of shares to close out the covered syndicate short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Transactions to close out the covered syndicate short involve either purchases of the common stock in the open market after the distribution has been completed or the exercise of the over-allotment option. The underwriters may also make “naked” short sales of shares in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of bids for or purchase of shares in the open market while the offering is in progress.

The underwriters also may impose a penalty bid. Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when ThinkEquity Partners LLC repurchases shares originally sold by the syndicate member in order to cover syndicate short positions or make stabilizing purchases.

Any of these activities may have the effect of preventing or retarding a decline in the market price of the common stock. They may also cause the price of the common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on the NASDAQ Capital Market or in the over-the-counter market, or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

We estimate that our total expenses of this offering will be approximately $2,080,000.

A prospectus in electronic format may be made available by one or more of the underwriters on a website maintained by a third-party vendor.

Other than the prospectus in electronic format, the information on such website is not part of the prospectus.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933 or to contribute to payments the underwriters may be required to make because of any of those liabilities.

We have agreed to sell to the representatives, for nominal consideration, a warrant (Underwriters’ Warrant) to purchase up to a total of 150,000 shares of our common stock. The Underwriters’ Warrant is not exercisable during the first year after the date of this prospectus and thereafter is exercisable at an exercise price equal to 125% of the public offering price per share set forth on the cover of this prospectus for a period commencing on the first anniversary of the date of

this prospectus and ending on the fifth anniversary of the date of this prospectus. The Underwriters' Warrant contains customary antidilution provisions and certain demand and participatory registration rights. The Underwriters' Warrant also includes a "cashless" exercise provision entitling the holder to convert the Underwriters' Warrant into shares of our common stock. The Underwriters' Warrant may not be sold, transferred, assigned or hypothecated for a period of one year from the date of this prospectus, except to officers or partners of the underwriters and members of the selling group and/or their officers or partners.

Legal matters

The validity of the common stock being offered hereby is being passed upon for us by Dreier LLP, New York, New York. We have received certain advice from our legal counsel in connection with the matters described herein. Certain legal matters relating to the offering will be passed upon for the underwriters by Greenberg Traurig, LLP, New York, New York. Prospective investors should consult with their own legal and other counsel.

Experts

The financial statements of Electro-Optical Sciences, Inc. as of December 31, 2003 and 2004, and for each of the three years in the period ended December 31, 2004, as set forth in their report, have been included herein and in the Registration Statement in reliance upon the report of Eisner LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

Where you can find more information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, 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. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document. When we complete this offering, we will also be required to file annual, quarterly and special reports, proxy statements and other information with the SEC. We anticipate making these documents publicly available, free of charge, on our website at www.eo-sciences.com as soon as reasonably practicable after filing such documents with the Securities and Exchange Commission.

You can read the registration statement and our future filings with the SEC, over the internet at the SEC's website at http://www.sec.gov. You may also read and copy any document that we file with the Securities and Exchange Commission at its public reference room at 100 F Street, N.E., Washington, DC 20549-1004.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549-1004. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference room.

Contents

Financial Statements:

Report of independent registered public accounting firm

The Board of Directors and Stockholders
Electro-Optical Sciences, Inc.

We have audited the accompanying balance sheets of Electro-Optical Sciences, Inc. (the “Company”) as of December 31, 2004 and 2003, and the related statements of operations, stockholders’ (deficiency) equity and cash flows for each of the years in the three year period ended December 31, 2004. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Electro-Optical Sciences, Inc. as of December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 13, the Company has restated its financial statements as of December 31, 2004 and for the year then ended to adjust for the recalculation of the fair value of warrants and a related beneficial conversion feature.

Eisner LLP

New York, New York
May 31, 2005, except as to Notes 8 and 13,
the date of which is August 3, 2005, and Note 1
(Reverse Stock Split and Conversion of Preferred Stock),
the date of which is September 27, 2005

Electro-Optical Sciences, Inc.

Balance sheets

	December 31, 2003 (Audited)	December 31, 2004 (Audited) (Restated Note 13)	June 30, 2005 (Unaudited) (Restated Note 13)	Pro-forma June 30, 2005 (Unaudited) (Note 1)
ASSETS				
Current Assets:				
Cash and cash equivalents	$ 116,691	$ 108,705	$ 176,208	$ 176,208
Marketable securities	—	6,594,751	3,617,713	3,617,713
Accounts receivable, net	16,679	7,128	—	—
Inventories	72,865	69,755	—	—
Prepaid expenses and other current assets	10,697	32,844	23,550	23,550
Assets held for sale	—	—	156,677	156,677
Deferred registration costs	—	—	752,042	752,042
Total Current Assets	216,932	6,813,183	4,726,190	4,726,190
Property and equipment, net	18,418	89,306	154,510	154,510
Patents and trademarks, net	178,157	163,459	86,517	86,517
Other assets	18,248	30,201	30,201	30,201
Total Assets	$ 431,755	$ 7,096,149	$ 4,997,418	$ 4,997,418
LIABILITIES AND STOCKHOLDERS' (DEFICIENCY) EQUITY				
Current Liabilities:				
Accounts payable (includes related parties of $2,000 as of December 31, 2004, and $79,645 as of June 30, 2005)	$ 211,810	$ 338,821	$ 233,504	$ 233,504
Accrued expenses	363,270	228,583	339,283	339,283
Accrued registration costs	—	—	672,873	672,873
Deferred revenues	—	106,335	—	—
Notes payable — stockholders and employees	48,000	—	—	—
Notes payable — other	15,000	—	—	—
Other current liabilities	11,976	17,284	—	—
Total Current Liabilities	650,056	691,023	1,245,660	1,245,660
REDEEMABLE CONVERTIBLE PREFERRED STOCK				
Redeemable preferred stock Series B convertible 992,986 shares designated (liquidation preference $2.26 per share); issued and outstanding 992,986 shares at December 31, 2003 and 2004 and June 30, 2005 and 0 shares at June 30, 2005, pro forma	2,244,147	2,244,147	2,244,147	—
Redeemable preferred stock Series C convertible 5,744,340 shares designated (liquidation preference $2.26 per share); issued and outstanding 907,077 shares at December 31, 2003 and 5,414,779 shares at December 31, 2004 and June 30, 2005 and 0 shares at June 30, 2005, pro forma	1,822,950	7,711,027	8,357,522	—
COMMITMENTS AND CONTINGENCIES				
Stockholders' (Deficiency) Equity:				
Preferred stock — $.10 par value; authorized 16,936,704 shares:				
Series A convertible preferred stock, 199,380 shares designated — (liquidation preference $5.00 per share); issued and outstanding 198,000 shares at December 31, 2003 and 2004 and June 30, 2005 and 0 shares at June 30, 2005, pro forma	972,311	972,311	972,311	—
Common stock — $.001 par value; authorized 30,000,000 shares; issued and outstanding 1,684,760 shares at December 31, 2003 and 1,809,758 shares at December 31, 2004 and June 30, 2005 and 6,513,164 shares at June 30, 2005, pro forma	1,685	1,810	1,810	6,513
Additional paid-in capital	5,119,923	9,611,094	9,035,398	20,604,675
Notes receivable for stock subscriptions	(69,000)	(69,000)	—	—
Deferred compensation	(22,500)	(159,300)	(143,370)	(143,370)
Accumulated deficit	(10,287,817)	(13,906,963)	(16,716,060)	(16,716,060)
Stockholders' (Deficiency) Equity	(4,285,398)	(3,550,048)	(6,849,911)	3,751,758
Total Liabilities and Stockholders' (Deficiency) Equity	$ 431,755	$ 7,096,149	$ 4,997,418	$ 4,997,418

See accompanying notes to financial statements

Statements of operations

Restated Note 13

	Year ended			Six months ended	
	December 31, 2002 (Audited)	December 31, 2003 (Audited)	December 31, 2004 (Audited) (Restated Note 13)	June 30, 2004 (Unaudited)	June 30, 2005 (Unaudited) (Restated Note 13)
Revenue from grants	$ 547,290	$ —	$ —	$ —	$ —
Operating expenses:					
Cost of grant revenue	563,598	—	—	—	—
General and administrative expenses	511,225	1,034,397	1,234,210	639,079	995,931
Research and development	404,331	828,239	1,891,551	693,052	1,545,824
Operating loss from continuing operations	(931,864)	(1,862,636)	(3,125,761)	(1,332,131)	(2,541,755)
Interest income	(2,189)	(1,373)	(27,935)	(543)	(62,769)
Interest expense	10,117	76,923	94,976	82,340	—
	7,928	75,550	67,041	81,797	(62,769)
Loss from continuing operations	(939,792)	(1,938,186)	(3,192,802)	(1,413,928)	(2,478,986)
Loss from discontinued operations	(201,259)	(11,917)	(426,344)	(101,853)	(330,111)
Net loss	(1,141,051)	(1,950,103)	(3,619,146)	(1,515,781)	(2,809,097)
Less:					
Preferred stock deemed dividends	214,245	321,830	676,218	242,693	719,064
Preferred stock accretion	180,009	25,228	257,545	25,228	646,496
Stock distribution of preferred Series B shares	—	101,700	—	—	
Net Loss Attributable to Common Stockholders	$ (1,535,305)	$ (2,398,861)	$ (4,552,909)	$ (1,783,702)	$ (4,174,657)
Net loss per share, basic and diluted:					
Continuing operations	(0.87)	(1.48)	(2.34)	(0.98)	(2.13)
Discontinued operations	(0.13)	(0.01)	(0.24)	(0.06)	(0.18)
Basic and diluted net loss per common share	$ (1.00)	$ (1.49)	$ (2.58)	$ (1.04)	$ (2.31)
Basic and diluted weighted average number of shares outstanding	1,534,760	1,614,897	1,766,608	1,722,743	1,809,758
Pro forma basic and diluted loss from continuing operations per common share (unaudited)			$ (0.80)		$ (0.38)
Pro forma basic and diluted weighted average number of common shares outstanding (unaudited)			3,967,024		6,513,164

See accompanying notes to financial statements

Statement of stockholders' (deficiency) equity

Years ended December 31, 2002, 2003 and 2004, and the six months ended June 30, 2005 (unaudited) (Restated Note 13)

	Convertible preferred stock Series A		Common stock		Additional paid-in capital	Notes receivable	Deferred compensation	Accumulated deficit	Total stockholders' (deficiency)
	Shares	Amount	Shares	Amount					
Balance at January 1, 2002	198,000	$ 972,311	1,534,760	$ 1,535	$ 2,932,174		$ (117,000)	$ (7,196,663)	$ (3,407,643)
Amortization of deferred compensation							72,000		72,000
Net loss								(1,141,051)	(1,141,051)
Preferred stock accretion					(180,009)				(180,009)
Balance at December 31, 2002	198,000	$ 972,311	1,534,760	$ 1,535	$ 2,752,165	—	$ (45,000)	$ (8,337,714)	$ (4,656,703)
Preferred stock accretion					(25,228)				(25,228)
Amortization of deferred compensation							22,500		22,500
Issuance of common stock in exchange for notes receivable			150,000	150	68,850	(69,000)			—
Adjustment for reduction to liquidation value of Series B preferred stock					2,329,000				2,329,000
Stock distribution of preferred Series B shares					(101,700)				(101,700)
Common stock options issued for consulting fees					96,836				96,836
Net loss								(1,950,103)	(1,950,103)
Balance at December 31, 2003	198,000	$ 972,311	1,684,760	$ 1,685	$ 5,119,923	$ (69,000)	$ (22,500)	$ (10,287,817)	$ (4,285,398)
Sale of common stock			124,998	125	137,375				137,500
Deferred compensation-stock option awards to employees					159,300		(159,300)		—
Issuance of options to non-employee directors					150,450				150,450
Preferred stock accretion					(257,545)				(257,545)
Warrants issued in connection with preferred Series C stock					2,643,392				2,643,392
Beneficial conversion feature in connection with preferred Series C stock					1,465,003				1,465,003
Issuance of options to consultants					72,800				72,800
Issuance of warrants to consultant					120,396				120,396
Amortization of deferred compensation							22,500		22,500
Net loss								(3,619,146)	(3,619,146)
Balance at December 31, 2004	198,000	$ 972,311	1,809,758	$ 1,810	$ 9,611,094	$ (69,000)	$ (159,300)	$ (13,906,963)	$ (3,550,048)
Preferred stock accretion					(646,496)				(646,496)
Value of options vesting on attainment of milestone					70,800				70,800
Retirement of note receivable						69,000			69,000
Amortization of deferred compensation							15,930		15,930
Net loss								(2,809,097)	(2,809,097)
Balance at June 30, 2005 (unaudited)	198,000	$ 972,311	1,809,758	$ 1,810	$ 9,035,398	$ —	$ (143,370)	$ (16,716,060)	$ (6,849,911)

See accompanying notes to financial statements

Statements of cash flows

	Year ended			Six months ended	
	December 31, 2002	December 31, 2003	December 31, 2004	June 30, 2004	June 30, 2005
	(audited)	(audited)	(audited)	(unaudited)	(unaudited)
Cash flows from operating activities:					
Loss from continuing operations	$ (939,792)	$ (1,938,186)	$ (3,192,802)	$ (1,413,928)	$ (2,478,986)
Loss from discontinued operations	(201,259)	(11,917)	(426,344)	(101,853)	(330,111)
Net loss	$ (1,141,051)	$ (1,950,103)	$ (3,619,146)	$ (1,515,781)	$ (2,809,097)
Adjustments to reconcile net loss to net cash used in operating activities:					
Allowance for doubtful accounts	—	(13,288)	(9,000)	—	(1,000)
Depreciation and amortization	33,329	30,987	35,860	14,578	25,098
Noncash compensation and amortization of deferred compensation	72,000	22,500	172,950	11,250	86,730
Common stock options and warrant issued for consulting fees	—	96,836	193,196	—	—
Retirement of stock subscription receivable for consulting services	—	—	—	—	34,500
Amortization of discount on marketable securities	—	—	(10,001)	—	(30,072)
Imputed interest expense attributable to preferred Series C	—	45,000	—	—	—
Imputed interest expense on bridge loan	—	—	80,000	80,000	—
Changes in operating assets and liabilities:					
(Increase) decrease in receivables	(3,326)	53,585	20,662	(64,794)	8,128
Decrease (increase) in inventories	67,279	(39,296)	3,110	(8,826)	(16,122)
Decrease (increase) in prepaid expenses and other current assets	6,060	(3,464)	(36,211)	(4,768)	9,293
Deferred registration costs	—	—	—	—	(79,169)
Increase (decrease) in accounts payable and accrued expenses	237,660	137,414	(7,676)	(76,936)	5,382
(Decrease) increase in deferred revenues	—	(57,300)	106,335	10,000	(106,335)
Increase (decrease) in other current liabilities	44,373	(21,879)	5,308	(11,976)	(17,284)
Net cash used in operating activities	(683,676)	(1,699,008)	(3,064,613)	(1,567,253)	(2,889,948)
Cash flows from investing activities:					
Patent costs	—	(5,986)	(3,166)	(2,712)	(2,822)
Purchases of property and equipment	—	(2,432)	(88,884)	(6,050)	(81,337)
Maturities (purchase) of marketable securities	518,050	—	(6,584,750)	—	3,007,110
Net cash provided by (used in) investing activities	518,050	(8,418)	(6,676,800)	(8,762)	2,922,951
Cash flows from financing activities:					
Proceeds from issuance of Series C preferred stock	—	1,500,000	9,171,480	1,100,000	—
Expenses related to Series C preferred stock offering	—	(252,278)	(447,553)	—	—
Proceeds from (repayment of) notes payable to stockholders	—	48,000	(48,000)	—	—
Proceeds from issuance of notes payable	—	520,000	920,000	920,000	—
Proceeds from sale of common stock	—	—	137,500	137,500	—
Payment for stock subscription receivable			—	—	34,500
Net cash provided by financing activities	—	1,815,722	9,733,427	2,157,500	34,500
Net (decrease) increase in cash and cash equivalents	(165,626)	108,296	(7,986)	581,485	67,503
Cash and cash equivalents at beginning of period	174,021	8,395	116,691	116,691	108,705
Cash and cash equivalents at end of period	$ 8,395	$ 116,691	$ 108,705	$ 698,176	$ 176,208
Supplemental Cash Flow Information:					
Cash paid for interest	$ —	$ 24,378	$ 14,976	$ —	$ —
Supplemental Schedule of Noncash Financing Activities:					
Notes payable exchanged for Series C preferred stock	$ —	$ 505,000	$ 1,015,000	$ —	$ —
Notes receivable received for common stock	$ —	$ 69,000	$ —	$ —	$ —
Preferred stock accretion	$ 180,009	$ 25,228	$ 257,545	$ 25,228	$ 646,496
Reduction to liquidation value Series B preferred stock		$ 2,329,000			
Beneficial conversion feature in connection with Series C preferred stock			$ 1,465,003		
Fair value of warrants issued in connection with Series C preferred stock			$ 2,643,392		
Accrued registration costs					$ 672,873
Reclassification of inventories and patents to assets held for sale					$ 156,677

See accompanying notes to financial statements

Notes to financial statements

(In thousands, except for share and per share data)
(Information for the six months ended June 30, 2004 and 2005 is unaudited)

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

Organization and Business

Electro-Optical Sciences, Inc., a Delaware corporation (the "Company") is focused on the design and development of a non-invasive, point-of-care instrument for assisting in the early diagnosis of melanoma. The Company has entered into a Protocol Agreement with the Food and Drug Administration (FDA) which is an agreement for the conduct of the pivotal trial and to establish the safety and effectiveness of the MelaFind® device. Upon obtaining premarket approval, or PMA, from the FDA, the Company plans to launch MelaFind® in the United States.

To date the Company has not generated any revenues from MelaFind®. All of the Company's historical revenues have come from activities and products that have since been discontinued, including our DIFOTI® product, a non-invasive imaging device for the detection of dental cavities. The Company discontinued all operations associated with its DIFOTI® product effective as of April 5, 2005, in order to focus its resources on the development and commercialization of MelaFind®. The Company is currently seeking a buyer for the DIFOTI® assets, and does not expect to have any significant continuing responsibility for the DIFOTI® business after the sale of the DIFOTI® assets. (See note 12)

The Company faces certain risks and uncertainties, which are present in many emerging medical device companies. At June 30, 2005, the Company has an accumulated deficit of $16,716 and anticipates that it will continue to incur net losses for the foreseeable future in the development and commercialization of the Melafind® device. In the event that the proposed initial public offering equity financing may not be available in amounts or on terms acceptable to the Company, the Company would need to pursue alternate sources of funding to sustain the continued development of the MelaFind® device at the same level, or to limit the level of discretionary expenditures.

Interim Financial Statements

The accompanying balance sheet as of June 30, 2005, and the statements of operations, stockholders' equity (deficiency) and cash flows for the six months ended June 30, 2004 and 2005 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's financial position and results of operations and cash flows for the six months ended June 30, 2004 and 2005. The financial data and other information disclosed in these notes to financial statements related to the six month periods are unaudited. The results for the six months ended June 30, 2005 are not necessarily indicative of the results to be expected for the year ending December 31, 2005.

Pro Forma Balance Sheet

The Pro Forma Balance Sheet gives effect as of June 30, 2005 to the conversion of all of the Company's outstanding preferred stock into 3,398,105 shares of common stock which will occur upon the closing of the proposed initial public offering. Upon such conversion, the deemed dividends on the convertible preferred stock will be forfeited. Additionally, it is assumed for pro forma purposes that 2,610,643 of the Company's warrants to purchase the Company's common stock will be exchanged for a total of 1,305,321 shares of the Company's common stock based on an exchange ratio of one share of the Company's common stock for every two shares of the Company's common stock purchaseable under the warrants and will occur prior to the closing of the proposed initial public offering.

Reverse Stock Split and Conversion of Preferred Stock

The Board of Directors approved on May 13, 2005, a one-for-two reverse stock split, which became effective subsequent to June 30, 2005. All references to common stock, common shares outstanding, average number of common shares outstanding, per share amounts, common stock options and warrants in these financial statements and notes to financial statements have been restated to reflect the one-for-two common stock reverse split on a retroactive basis.

In September 2005 the effective date of the automatic conversion of the Company's designated preferred stock was changed to the date of completion of the Company's initial public offering.

Cash and Cash Equivalents

The Company maintains cash in bank deposit accounts which, at times, may exceed federally insured limits. The Company has not experienced any losses on these accounts. Cash equivalents include all highly-liquid debt instruments with an original maturity of three months or less at the date of acquisition.

Marketable Securities

Marketable securities consist of debt securities that the Company has the intent and ability to hold to maturity. The Company classifies the marketable securities as held-to-maturity in accordance SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Held-to-maturity securities are recorded at amortized cost.

Accounts Receivable

Accounts receivable are reported at their outstanding unpaid principal balances reduced by an allowance for doubtful accounts. The Company estimates doubtful accounts based on historical bad debts, factors related to specific customers' ability to pay and current economic trends. The Company writes off accounts receivable against the allowance when a balance is determined to be uncollectible.

Inventories

Inventories, which consist primarily of DIFOTI® supplies, are stated at the lower of cost, determined by the first-in, first-out method, or market.

Assets Held for Sale

Assets held for sale at June 30, 2005 consisted of DIFOTI® related inventories and patents.

Deferred Registration Costs

The costs associated with the Company's proposed initial public offering have been recorded as deferred registration costs and will reduce additional paid-in capital if the offering is effective. Should the offering not be consummated, the deferred registration costs will be recognized as a charge to operations.

Property and Equipment

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

Patents

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

Revenue Recognition

During April 2005, the Company discontinued the sale of the DIFOTI® product line. (Note 12). Revenue from DIFOTI® product sales was recognized at the time of delivery and acceptance, and after consideration of all the terms and conditions of the customer contract. Certain of the Company's products which were being sold prior to December 31, 2004 included a 30-day return policy. Revenue on these products was recognized after the shipment was made and the 30-day return period had elapsed. Effective January 1, 2005 all products were sold without a right of return and revenue was therefore recognized upon shipment. Deferred revenues at December 31, 2004 consisted of revenues that were billed and paid in advance of the shipment of the product.

The Company has not received FDA approval for the sale of MelaFind® and has had no revenues from products other than DIFOTI®.

Grant revenue generated in 2002 represents federal grants received by the Company in conjunction with an undertaking to perform certain research. The cost of grant revenue consists primarily of payroll and related costs amounting to $564.

Warranty Costs

The Company generally warranted its only commercialized product, DIFOTI®, for one year after the sale had been completed. Through March 31, 2005, warranty costs were de minimus, and were recorded by the Company as incurred. During the quarter ended June 30, 2005, in connection with the discontinuance of its DIFOTI® product line, the Company recorded a reserve for warranty expense in accordance with the requirements of Statement of Financial Accounting Standards No. 5 "Accounting for Contingencies" (SFAS No. 5), in the amount of $20 since the Company believes it is probable that such discontinuance will lead to warranty claims. As of June 30, 2005, prior sales of approximately $200 were subject to possible warranty claims.

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the amounts of existing assets and liabilities recorded in the financial statements and their respective tax bases and the benefits arising from the realization of operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

Estimates

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

Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition exceeds its carrying amount. The amount of impairment loss, if any, is measured as the difference between the net book value of the asset and its estimated fair value.

Research and Development

Research and development costs are expensed as incurred.

Stock-Based Compensation

The Company applies the intrinsic-value method of accounting prescribed by the Accounting Principles Board (APB) Opinion No. 25 and related interpretations to account for the Company's fixed-plan employee stock options. Under this method, compensation expense is recorded on the date of grant only if the then current market price of the underlying stock exceeded the exercise price. Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*, established accounting and disclosure requirements using a fair-value based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123 and No. 148, the Company has elected to continue to apply the intrinsic-value based method of accounting for employee stock options described above, and has adopted only the disclosure requirements of SFAS No. 123. Had the Company elected to recognize compensation cost based on the fair value of the options granted at the grant date, as prescribed by SFAS No. 123, the Company's net loss and net loss per share would have been adjusted to the pro forma amounts indicated below:

	December 31,			June 30,	
	2002	2003	2004	2004	2005
Net loss attributable to common stockholders, as reported	$ (1,535)	$ (2,399)	$ (4,553)	$ (1,784)	$ (4,175)
Add: stock-based employee compensation included in reported net loss, net of income tax effect	72	23	173	11	87
Deduct: stock-based employee compensation expense determined under fair-value-based method, net of related tax effect	(75)	(65)	(186)	(8)	(90)
Pro forma net loss	$ (1,538)	$ (2,441)	$ (4,566)	(1,781)	$ (4,178)
Basic and diluted loss per share, as reported	$ (1.00)	$ (1.49)	$ (2.58)	$ (1.04)	$ (2.31)
Basic and diluted loss per share, pro forma	$ (1.00)	$ (1.51)	$ (2.58)	$ (1.04)	$ (2.31)

The per share weighted-average fair value of stock options granted during 2002, 2003 and 2004 was $.26, $.34, and $3.00, respectively, on the dates of grant using the Black-Scholes option-pricing model.

During the six months ended June 30, 2005, the Company did not grant any stock options. The per share weighted average fair value of stock options granted during the six months ended June 30, 2004 was determined using the Black-Scholes option pricing model resulting in a weighted average fair value of $0.25 per share. The following weighted-average assumptions were used:

	December 31,			June 30,	
	2002	2003	2004	2004	2005
Expected volatility	1%	1%	60%	60%	—
Risk-free interest rate	4.52% to 5.43%	4.52% to 5.43%	3.17% to 3.94%	3.39%	
Expected option life (in years)	10	10	5	5	
Expected dividend yield	0%	0%	0%	0%	

Options or warrants issued to non-employees for services are recorded at fair value and accounted for in accordance with Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. For equity instruments that are not immediately vested, compensation cost is measured on the date such instruments vest or a performance commitment,

as defined in EITF 96-18, is reached. The costs are classified in the accompanying statements of operations based on the nature of the services performed.

Deferred Compensation

Deferred compensation attributable to unvested common stock options is measured at the measurement date for the respective grants, and reflected as a deduction from stockholders' equity. Compensation expense is recognized ratably over the vesting period.

Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable and accounts payable. The Company believes the financial instruments' recorded values approximate current values because of their nature and respective durations. The Company maintains cash in bank deposit accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses on these accounts.

Net Loss per Common Share

Net loss per share is presented in accordance with the provisions of SFAS No. 128, "Earnings Per Share" (EPS). Basic EPS excludes dilution for potentially dilutive securities and is computed by dividing loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to dilutive options, warrants and other potential common shares outstanding during the period. Diluted net loss per common share is equal to basic net loss per common share since all potentially dilutive securities are anti-dilutive for each of the periods presented. Diluted net loss per common share for the years ended December 31, 2002, 2003 and 2004 does not include the effects of options to purchase 142,581, 290,678 and 965,203 shares of common stock, respectively and 407,182 and 899,875 shares for the six months ended June 30, 2004 and 2005 respectively; 690, 369,993 and 2,758,923 common stock warrants for the years ended December 31, 2002, 2003 and 2004, respectively, and 673,662 and 2,758,923 common stock warrants for the six months ended June 30, 2004 and 2005, respectively.

The pro forma basic and diluted loss from continuing operations per common share for the year ended December 31, 2004 and for the six months ended June 30, 2005 gives effect to the conversion of the existing shares of preferred stock into 3,398,105 shares of common stock at the conversion ratios which would apply upon consummation of the proposed initial public offering and the exchange of 2,610,643 warrants for 1,305,321 shares of common stock as described in Note 9. In addition, the loss from continuing operations used in the computation of unaudited pro forma basic and diluted loss from continuing operations per share has been adjusted to reverse the accretion on the Company's preferred stock and also excludes the preferred stock dividends for the respective periods.

Recently Issued Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued the revised SFAS No. 123, Share-Based Payment (SFAS 123R), which addresses the accounting for share-based payment transactions in which the Company obtains employee services in exchange for (a) equity instruments of the Company or (b) liabilities that are based on the fair value of the Company's equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123R eliminates the ability to account for employee share-based payment transactions using APB No. 25 and requires instead that such transactions be accounted for using the grant-date fair value based method. SFAS 123R will be effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 (January 1, 2006 for the Company) and applies to all awards granted or modified after the effective date. In addition, compensation cost for the unvested portion of previously granted awards that remain outstanding on the effective date shall be recognized on or after the effective date, as the related services are rendered, based on the awards' grant-date fair value as previously calculated for the pro-forma disclosure under SFAS 123. The Company expects that upon the adoption of SFAS 123R it will apply the modified prospective application transition method, as permitted by the statement. Under such transition method, upon the adoption of SFAS 123R, the Company's financial statements for periods prior to the effective date of the statement will not be restated. The impact of this statement on the Company's

financial statements or its results of operations in 2005 and beyond will depend upon various factors, among them, its future compensation strategy. The Company expects that the effect of applying this statement on its results of operations in 2005 as it relates to existing option plans would not be materially different from the SFAS 123 pro forma effect previously reported.

In March 2004, the FASB issued EITF Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," which provides new guidance for assessing impairment losses on debt and equity investments. Additionally, EITF Issue No. 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF Issue No. 03-1; however, the disclosure requirements remain effective and have been adopted by the Company in the financial statements. The Company will evaluate the effect, if any, of EITF Issue No. 03-1 when final guidance is released.

2. Marketable Securities:

The Company's investments mature within one year. Investments in marketable securities are summarized as follows at December 31, 2004 and June 30, 2005:

	December 31, 2004			June 30, 2005		
	Gross unrealized loss	Fair value	Amortized cost	Gross unrealized loss	Fair value	Amortized cost
Corporate commercial paper	$ —	$ 2,500	$ 2,500	$ —	$ —	$ —
Corporate debt	(10)	2,497	2,507	(2)	2,024	2,026
United States Treasury note	(8)	1,580	1,588	(7)	1,585	1,592
	$ (18)	$ 6,577	$ 6,595	$ (9)	$ 3,609	$ 3,618

3. Property and Equipment:

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

	December 31,		June 30,	Estimated
	2003	2004	2005	useful life
Leasehold improvements	$ 23	$ 32	$ 65	5-10 years
Laboratory and research equipment	61	119	119	5 years
Office furniture and equipment	113	135	184	5 years
	197	286	368	
Less accumulated depreciation and amortization	179	197	213	
	$ 18	89	$ 155	

Depreciation expense amounted to approximately $16, $15 and $18, for the years ended December 31, 2002, 2003 and 2004, respectively and $6 and $15 for the six months ended June 30 2004 and 2005 respectively.

4. Patents:

Patents are shown in the accompanying balance sheets net of accumulated amortization of $83 and $101 at December 31, 2003 and 2004, respectively. At June 30, 2005, accumulated amortization applicable to patents in use amounted to $61. In connection with the discontinuance of DIFOTI® operations in April 2005, patents with a net book value of $71 have been reclassified as assets held for sale. Amortization expense related to the patents was approximately $17, $17 and $18 for the years ended December 31, 2002, 2003 and 2004, respectively and $9 and $10 for the six months ended June 30, 2004 and 2005, respectively.

The estimated future amortization expense related to the patents is as follows:

Year ended December 31,	
2005	$ 14
2006	10
2007	10
2008	10
2009	10
Thereafter	40
	$ 94

5. Notes Payable-Stockholders:

During 2003, the Company had notes payable to two of its stockholders totaling $48. These notes were payable in October 2004, bore interest at 6%, and were repaid during 2004. Interest expense amounted to approximately $1 and $2 for the years ended December 31, 2003 and 2004, respectively. In addition, the Company had a demand note payable to one of its stockholders in the amount of $15 with interest accruing at 12% per annum. During October 2004, the note and accrued interest of $1 were converted into 6,999 shares of Series C preferred stock.

6. Commitments and Contingencies:

The Company is obligated under two non cancelable operating leases for office space expiring June 2009 and November 2010. The leases are subject to escalations for increases in operating expenses. The approximate aggregate minimum future payments under these leases are due as follows:

Year ended December 31,	
2005	$ 205
2006	204
2007	213
2008	217
2009	170
Thereafter	105
	$ 1,114

Rent expense charged to operations amounted to approximately $88, $113 and $110 for the years ended December 31, 2002, 2003 and 2004, respectively, and $54 and $94 for the six months ended June 30, 2004 and 2005, respectively.

During January 2004, the Company entered into an employment agreement with its President and Chief Executive Officer through December 31, 2005, which provides for a base salary of $175, stock options and performance bonuses. The agreement provides for automatic one year renewal terms.

During January 2004 the Company amended its employment agreement with its former president, who now holds the title Chief Science and Technology Officer. The agreement was originally entered into in May 2003 with a three-year term. The agreement now includes a salary of $175 and provides for stock options and performance bonuses. As of May 31, 2005, this former employee is now a consultant to the Company.

The Company had been involved in various claims and legal actions arising in the ordinary course of business. The ultimate outcome of these matters did not have a material adverse impact on the financial position of the Company or the results of its operations.

7. Employee Benefit Plan:

The Company has a defined contribution plan under Section 401(k) of the Internal Revenue Code covering all qualified employees. An officer of the Company serves as trustee of the plan. The Company provides a matching contribution of up to 3% of each employee's salary. Contributions to this plan amounted to approximately $29, $12 and $25 for the years ended December 31, 2002, 2003 and 2004, respectively, and $11 and $15 for the six months ended June 30, 2004 and 2005, respectively.

8. Stockholders' (Deficiency) Equity and Redeemable Preferred Stock (as restated — see Note 13):

During January 2003, the Company received $180 in exchange for issuing a convertible promissory note bearing interest at 10% per annum, The note was convertible at a discount of 20% on the next round of financing. In June 2003, the note was converted into Series C redeemable convertible preferred stock. (See discussion below.) Upon conversion of the note the Company recorded a charge of $45 to reflect the value of the beneficial conversion of the shares since the shares were converted at $1.81 per share, a 20% discount. In addition, the Company granted the note holder five-year warrants to purchase 25% of the total number of securities issued upon conversion of the note, which amounted to 99,558 shares (or 24,890 warrants), at an exercise price equal to the per share price of the next financing as defined in the loan agreement. The value of these warrants was de minimus. For the year ended December 31, 2003, interest on these notes amounted to approximately $8.

During February 2003, certain stockholders loaned the Company $325 bearing interest at 12% per annum. In June 2003, these loans were converted into 143,802 shares of Series C redeemable convertible preferred stock at $2.26 per share. For the year ended December 31, 2003, interest on these notes amounted to approximately $21.

During June 2003, the Company completed a private placement whereby investors agreed to acquire up to 1,400,000 preferred Series C units. Each unit consists of one share of Series C redeemable convertible preferred stock and one warrant to purchase one share of common stock at an exercise price of $13.00 per share. Of the 1,400,000 units, the first tranche of 663,717 units was sold for an aggregate of $1,500. Costs associated with this issuance amounted to $252. This amount will be accreted to the Series C over the redemption period. For the year ended December 31, 2003, $25 was accreted. The value of the warrants was de minimus.

In order to complete the June 2003 private placement, the Series A and B stockholders consented to modifications to certain of their rights, preferences, and privileges. The Series A preferred shares were split 1,000 for 1 and due to the anti-dilution provision, the conversion ratio of Series A was changed to 0.5818 to 1 (totaling 16,202 shares of common stock). Additionally, the Company granted a stock distribution of 45,000 shares of Series B preferred stock to the Series B stockholders, valued at $102 or $2.26 per share. As a result of these modifications, the Company adjusted the carrying amount of the Series B preferred stock. Due to the anti-dilution provision, the conversion ratio of Series B was changed to 0.5796 to 1 (totaling 79,043 shares of common stock). The Series C redeemable convertible preferred stock converts to common stock at a ratio of 0.50 to 1.

In connection with the private placement, 150,000 shares of common stock were sold to the promoters, who are related parties, at $.46 per share. Notes of $69 were received for this purchase and is shown as a reduction in stockholders' equity (deficiency). The note bears interest at 3.06% and is due June 20, 2008. Interest income amounted to approximately $2 and $1 for the years ended December 31, 2004 and 2003, respectively. During June 2005, the notes of $69 were retired by a cash payment and consulting services rendered.

During 2004, the second tranche of the Series C private placement was completed and an additional 486,725 of Series C units were issued for total proceeds of $1,100. An additional 427 units were distributed in order to comply with minimum ownership provisions. The value of the distribution was de minimus. In order to induce the investment in this second tranche, the Company issued additional warrants to purchase 60,840 shares of Series C redeemable convertible preferred stock at a price of $4.52 per share. These warrants were valued at $179.

During May 2004, the Company obtained bridge loans in the amount of $1,000 from related parties. The loans bear interest at 1.57% and were payable on December 31, 2004. During October 2004 these loans were converted into 442,469 preferred Series C units at a price of $2.26 per unit. The warrants were valued at $327. The Company also

sold approximately 125,000 shares of common stock to the lenders at $.46 per share for $57. The Company ascribed a value to the common stock and recorded an imputed interest charge of $80.

During October 2004, the Company completed a second private placement and sold 3,578,081 preferred Series C units for total proceeds of approximately $8,100 at a price of $2.26 per unit. The warrants were valued at $2,653. Costs of the Series C private placement amounted to approximately $448. This amount will be accreted to the Series C over the redemption period.

During 2004, the Company issued 4,507,702 shares of Series C redeemable convertible preferred stock with 2,253,792 warrants to purchase common stock at $13.00 per share and 60,840 Series C redeemable convertible preferred stock warrants at an exercise price of $4.52 per share for gross proceeds of $10,186. The net proceeds of $9,738 were allocated to redeemable convertible preferred stock and additional paid-in capital based on the relative fair values of the preferred stock and warrants. The fair value of the warrants was determined using the Black-Scholes method. The assumptions used to value these warrants are described in Note 9. The Company recorded a beneficial conversion feature of $1,465 which is being accreted to redemption for the Series C redeemable convertible preferred stock based on the earliest redemption date of June 2008.

The total accretion to redemption value for the Series C amounted to $25, $258, and $647 for the years ended December 31, 2003 and 2004 and the six months ended June 30, 2005, respectively.

The following table summarizes the recorded accretion for the aforementioned periods:

	Total amount	Accretion period in months	Year ended December 31, 2003	Year ended December 31, 2004	Six months ended June 30, 2005
June 2003 Series C financing costs	$ 252	60	$ 25	$ 51	$ 25
Oct. 2004 Series C financing costs	448	44		20	61
Value of Series C warrants	2,643	44		120	361
Beneficial Conversion — Series C	1,465	44	—	67	200
Total	$ 4,808		$ 25	$ 258	$ 647

The rights, preferences, and privileges of the Series B and C redeemable preferred stock are as follows:

Voting Rights

All holders of redeemable convertible preferred stock have voting rights equal to the number of shares of common stock into which the respective preferred stock is convertible.

Liquidation Preference

In the event of liquidation, dissolution, or winding-up of the Company, and before any distribution to common stockholders, the holders of Series B and C redeemable convertible preferred stock are entitled to receive $2.26 per share plus all accrued but unpaid dividends.

Deemed Dividends

Dividends on the Series B and Series C redeemable convertible preferred stock may be declared at the discretion of the board of directors at an annual rate equal to 10%, as adjusted, of the accreted value per share and shall be payable in preference and priority to any declaration or payment of any distribution on Series A preferred stock or common stock and will be cumulative. At December 31, 2004 and June 30, 2005 there are approximately $1,510 and $2,229 of deemed but unpaid dividends. In the event the preferred stock is converted into common stock, any related deemed dividends would be forfeited.

Redemption Provisions

Pursuant to the modification of the Series B preferred stock terms adopted at the closing of the Series C private placement, the requirement to redeem the preferred shares, at the option of the holder, has been extended to June 2008. The redemption of Series B requires approval of the Series C shareholders. The preferred Series C stock is redeemable at the option of the holder, on the fifth and sixth anniversary of the first issuance of Series C preferred stock (June 2003). Series B has been classified as temporary equity at its redemption value; Series C has been so classified at its accreted value.

Series C Preferred Stock Carrying Value

The following table summarizes the changes in carrying amount of the Company's Series C redeemable convertible preferred stock for the year ended December 31, 2004, and the six months ended June 30, 2005.

Balance at December 31, 2003	$	1,823
Issuance of Series C preferred stock in 2004, less associated costs of $447, value of warrants sold therewith of $2,643, and allocation to beneficial conversion feature of $1,465		5,630
Preferred stock accretion		258
Balance at December 31, 2004	$	7,711
Preferred stock accretion		647
Balance at June 30, 2005	$	8,358

9. Stock Options and Warrants:

Warrants

Warrants outstanding consist principally of warrants issued in connection with the Company's Series C financing and generally expire seven years from the date of grant.

During 2003, in connection with the sale of Series C redeemable convertible preferred stock, 356,851 warrants to purchase common stock at an exercise price of $13.00 per share were issued. The fair value of these warrants was determined to be de minimus using the Black-Scholes method. The assumptions used in determining the fair value were the following: common stock value per share of $0.46, warrant life of 7 years, a risk-free interest rate of 3.67%, and an expected volatility of 1%. The Company also issued 12,445 warrants to purchase shares of Series C redeemable convertible preferred stock at an exercise price of $4.52. The fair value of these warrants was determined to be de minimus using the Black-Scholes method assuming a stock price of $4.52 per share, warrant life of 5 years, a risk-free interest rate of 3.67%, and an expected volatility of 1%.

During 2004, in connection with the sale of Series C redeemable convertible preferred stock, 2,253,792 warrants to purchase common stock at an exercise price of $13.00 per share were issued. The fair value of these warrants ranged from $0.02 to $1.48 using the Black-Scholes method. The assumptions used in determining the fair value were the following: common stock value per share ranged from $0.46 to $4.00, warrant life of 7 years, a risk-free interest rate of 3.67%, and an expected volatility of 60%. The Company also issued 60,840 warrants to purchase shares of Series C redeemable convertible preferred stock at an exercise price of $4.52. The fair value of these warrants was determined to be $2.94 using the Black-Scholes method assuming a stock price of $4.52 per share, warrant life of 7 years, a risk-free interest rate of 3.67%, and an expected volatility of 60%. The total fair value of the aforementioned warrants issued in 2004 aggregated $3,159.

During 2004, the Company issued a 5 year warrant to purchase 75,000 shares of common stock at an exercise price of $7.00 per share to one of its consultants. These warrants have been valued at $120 using the Black-Scholes method and was recorded as compensation expense. The assumptions used in determining the fair value were the following:

common stock value per share of $4.00, warrant life of 5 years, a risk-free interest rate of 3.67%, and an expected volatility of 60%.

Warrant activity during the periods indicated is as follows:

	Warrants	Weighted-average exercise price
Outstanding at January 1, 2002	10,505	$ 10.00
Expired	(9,815)	10.00
Outstanding at December 31, 2002	690	$ 10.00
Granted	369,303	12.72
Outstanding at December 31, 2003	369,993	12.70
Granted	2,389,620	12.60
Expired	(690)	10.00
Outstanding at December 31, 2004	2,758,923	$ 12.61

There was no warrant activity during the six months ended June 30, 2005.

On April 5, 2005, the Board of Directors approved, subject to stockholder approval, the issuance of 1,305,321 shares of the Company's common stock in exchange for 2,610,643 outstanding warrants (a conversion ratio of one share of common stock for two warrants.) The Company considers this transaction to be an exchange of equity instruments at fair value which will have no net effect on stockholders' equity. The fair value of the warrants was determined using the Black-Scholes method and assumed the following: common stock value of $10.00 per share, remaining warrant life of 6.25 years, risk-free interest rate of 3.2%, and an expected volatility of 60%.

Stock Options

The Company has three stock option plans (the "Plans") which allow the board of directors to grant incentives to employees, directors and collaborating scientists in the form of incentive stock options, nonqualified stock options and restricted stock. At December 31, 2004 and June 30, 2005, options to purchase 965,203 and 899,875 shares of common stock, respectively, at exercise prices ranging from $.40 to $10.00 per share are outstanding and are exercisable at various dates through 2013. The total number of shares reserved under the Company's stock option plans is 1,000,000.

In January 2003, the Company issued an option to acquire 24,209 shares of common stock at an exercise price of $1.00 per share valued at approximately $97 to outside consultants. During 2004, the Company issued options to acquire 27,750 shares of common stock at an exercise price of $.46 per share valued at approximately $73 to outside consultants. The fair value for these options granted to outside consultants was calculated using the Black-Scholes method. For the options granted during 2004 to outside consultants, the assumptions used in the Black-Scholes model were: common stock valued ranged from $0.46 to $4.00, expected life of 5 years, risk-free interest rate ranged from 3.39% to 3.94%, and an expected volatility of 60%.

During 2004 the Company issued 262,500 options to certain employees and Board members. The value of the options resulted in a charge to operations in the amount of $150 and $71 during the year ended December 31, 2004 and for the six months ended June 30, 2005, respectively. The share based compensation expense for these option grants represent the amount by which the fair value per common share of $4.00 exceeds the exercise price per share of $0.46.

Stock option activity during the periods indicated is as follows:

	Number of shares	Weighted-average exercise price
Outstanding at January 1, 2002	128,050	$ 2.28
Granted	14,531	1.00
Outstanding at December 31, 2002	142,581	2.16
Granted	158,565	.94
Expired/ Forfeited	(10,468)	.96
Outstanding at December 31, 2003	290,678	1.12
Granted	679,525	.46
Expired/ Forfeited	(5,000)	1.00
Outstanding at December 31, 2004	965,203	.66
Expired/ Forfeited	(65,328)	.89
Outstanding at June 30, 2005	899,875	$ .64
Options exercisable at December 31, 2004	428,729	$ .89
Options exercisable at June 30, 2005	446,675	.82

The following table summarizes information about fixed stock options outstanding at December 31, 2004:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted-average remaining contractual life	Weighted-average exercise price	Number exercisable	Weighted-average exercise price
$.01-$.46	694,525	4.7 years	$ .46	173,989	$ .46
$.47-$1.00	265,678	6.5 years	1.00	249,740	1.00
$1.01-$10.00	5,000	.4 years	10.00	5,000	10.00
$.01-$10.00	965,203	5.7 years	$ .66	428,729	$ .89

As of June 30, 2005, of the total 899,875 options outstanding, 445,701 of these options will vest upon the attainment of certain milestones and will be charged to operations based on the then current Company's market price per share.

The employment agreement with Dr. Gulfo includes three separate grants of common stock options. The first two stock option grants for a total of 81,753 shares of the Company's common stock have fully vested. The number of shares of the Company's common stock subject to the third stock option can only be calculated at the time of PMA approval of MelaFind®. The number of shares under this option is equal to that number of shares of our common stock equal to four percent of the Company's fully diluted capital stock at the time of PMA approval of MelaFind® minus the 81,753 options granted to Dr. Gulfo under the employment agreement.

In May 2005, the Company amended option agreements for 125,000 shares in the aggregate of three key employees to immediately vest upon the completion of a successful initial public offering. The Company will record a charge to operations based upon the initial public offering price.

10. Income Taxes:

At December 31, 2004 and June 30, 2005, the Company had net operating loss carryforwards of approximately $12,208 and $15,017, respectively, available to offset future taxable income expiring at various dates through the year 2025. The Company's ability to utilize its net operating losses may be significantly limited due to changes in the Company's ownership as defined by federal income tax regulations. Without regard to any such limitations, the Company had a deferred tax asset of approximately $3,443, $4,883 and $6,007 at December 31, 2003, 2004 and June 30, 2005, respectively. Because the Company anticipates continued losses for the foreseeable future, the Company has recorded a 100% valuation allowance against its deferred income tax assets for all periods. The increase in the valuation allowance for the years ended December 31, 2002, 2003, 2004 and six months ended on June 30, 2005 amounted to $428, $753, $1,440 and $1,124, respectively.

11. Related Party Consulting Agreements:

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

Consulting Agreement with Breaux Castleman

In June 2003, the Company entered into a consulting agreement with Breaux Castleman, the Chairman of the Company's Board of Directors, for consulting services related to the FDA approval of MelaFind®, and the Company's business and financial strategy. Under this agreement, Mr. Castleman receives compensation for each month of services rendered. The Company made payments pursuant to this consulting agreement $48 in 2003, $22 in 2004, and $12 through June 30, 2005. This consulting agreement is terminable by either party on 30 days' written notice.

Consulting Agreement with Marek Elbaum, Ph.D.

Pursuant to a consulting agreement effective as of May 31, 2005, the Company retained Marek Elbaum, Ph.D., the Company's founder and former Chief Science and Technology Officer, as the Company's Chief Scientist. In consideration of the services to be provided, the Company has agreed to pay Dr. Elbaum a monthly fee of $15. The term of this agreement extends for a period of two years and is automatically renewable for an additional one year period. In the event of a non-renewal, and in the event that Dr. Elbaum's services terminate as a result of his death or disability, we will pay to Dr. Elbaum a termination fee of $100.

Consulting Agreement with Robert Friedman, M.D.

Effective as of June 1, 2005, the Company retained the services of Robert Friedman, M.D., for an initial term of one year as a consultant, medical advisor to our Board of Directors, and in connection with the clinical testing of MelaFind®. In consideration for these services, Dr. Friedman will be paid at a rate of $5,000 per day. This consulting agreement is automatically renewed for successive one-year terms unless either party terminates the agreement at least 30 days prior to the expiration of the agreement.

Consulting Agreement with Gerald Wagner, Ph.D.

On June 1, 2005, the Company entered into a consulting agreement with Gerald Wagner, Ph.D., a member of the Company's Board of Directors, to direct our MelaFind® product development efforts and oversee the manufacturing process. The agreement ends three months following the initiation of the Company's pivotal clinical trial of MelaFind®. The consulting agreement provides for a flat fee of $150,000, payable ratably over the course of the term, and a stock option grant to purchase 50,000 shares of the Company's common stock, subject to and immediately after completion of the Company's initial public offering at the public offering price per share.

12. Discontinued Operations and Assets Held For Sale:

On March 9 through March 21, 2005, the Company was inspected by the FDA in connection with its DIFOTI® product, a non-invasive imaging device for the detection of dental cavities. On March 21, 2005, the Company was cited for

failures to comply fully with FDA quality system regulation, or QSR, mandated procedures. These inspectional findings were discussed in a subsequent meeting with the FDA on April 28, 2005.

The Company is in the process of addressing the deficiencies noted.

The Company decided to discontinue all operations associated with its DIFOTI® product effective as of April 5, 2005, in order to focus its resources and attention on the development and commercialization of MelaFind®. The Company is currently seeking an acquirer for the DIFOTI® assets, and does not expect to have any significant continuing responsibility for the DIFOTI® business after its disposition.

Losses attributable to DIFOTI® operations discontinued in April 2005 amounted to $201, $12, $426, $102, and $330 for the years ended December 31, 2002, 2003, 2004, and the six months ended June 30, 2004 and 2005, respectively.

SFAS No. 144 requires that long-lived assets to be disposed by sale be measured at the lower of carrying amount or fair value less cost to sell. SFAS No. 144 also broadened the reporting of discontinued operations to include all components of an entity with operations that will be eliminated from ongoing operations of the entity in a disposal transaction. At June 30, 2005, assets held for sale consisted of DIFOTI® related inventories and patents.

In accordance with the provisions of SFAS No. 144, the results of operations of the discontinued business have been reported as discontinued operations for all periods presented in the accompanying financial statements.

13. Revisions to Previously Issued Financial Statements as of and for the Year Ended December 31, 2004 and Six Months Ended June 30, 2005.

The Company has recomputed the relative fair value of warrants and related beneficial conversion feature in connection with the issuance of Series C preferred stock in October 2004 referred to in Note 8. Such recomputation resulted in a change in the preferred stock accretion for the historical year ended December 31, 2004 and the six months ended June 30, 2005. The following table summarizes the recomputation of the fair values.

	As previously reported	As restated	Adjustment
Value of warrants	$ 3,158,948	$ 2,643,392	$ 515,556
Value of beneficial conversion feature	2,385,063	1,465,003	920,060

A summary of the changes to the Company's previously issued financial statements is as follows:

	Series C preferred stock	Additional paid-in capital	Stockholders' (deficiency) equity
As previously reported, December 31, 2004	$ 6,340,666	$ 10,981,455	$ (2,179,687)
Adjustment of relative fair value of warrants issued with Series C preferred stock	515,556	(515,556)	(515,556)
Adjustment of amount of beneficial conversion feature	920,060	(920,060)	(920,060)
	1,435,616	(1,435,616)	(1,435,616)
Adjustment of accretion applicable to Series C preferred stock	(65,255)	65,255	65,255
As restated, December 31, 2004	$ 7,711,027	$ 9,611,094	$ (3,550,048)

	Series C preferred stock	Additional paid-in capital	Stockholders' (deficiency) equity
As previously reported, June 30, 2005	$ 7,182,925	$ 10,209,995	$ (5,675,314)
Net effect of above 2004 adjustments	1,370,361	(1,370,361)	(1,370,361)
Adjustment of accretion applicable to Series C preferred stock	(195,764)	195,764	195,764
As restated, June 30, 2005	$ 8,357,522	$ 9,035,398	$ (6,849,911)

Net loss attributable to common stockholders for the respective periods was reduced as follows as a result of reductions in preferred stock accretion:

	Year ended December 31, 2004		Six months ended June 30, 2005	
	Total	Per common share	Total	Per common share
As previously reported	$ (4,618,164)	$ (2.61)	$ (4,370,421)	$ (2.41)
Reduction in accretion applicable to preferred stock	65,255	.03	195,764	.10
As restated	$ (4,552,909)	$ (2.58)	$ (4,174,657)	$ (2.31)


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