SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2005

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 000-51481

ELECTRO-OPTICAL SCIENCES, INC

(Exact name of registrant as specified in its charter)

Delaware	**13-3986004**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3 West Main Street, Suite 201
Irvington, New York 10533
(Address, including zip code, of registrant's principal executive offices)
(914) 591-3783
Registrant's telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act:
None
Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value
(Title of class)

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Security Act. Yes o No ☑

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer o Non-accelerated filer ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☑

The registrant commenced trading following its initial public offering on October 28, 2005. The aggregate market value of the 9,105,783 shares of common stock held by non-affiliates of the registrant as of February 28, 2006 was $50,263,922 based on the last reported sale price of $5.52 per share on the Nasdaq Capital Market on February 28, 2006. (For this computation, the registrant excluded the market value of all the shares of its common stock held by Directors and Officers of the registrant and a certain shareholder holding approximately 10.1% of the registrant's shares outstanding; such exclusion shall not be deemed to constitute an admission that any such person is an "affiliate" of the registrant). The number of shares outstanding of the registrant's common stock as of February 28, 2006 was 10,865,917 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2006 Annual Meeting of Stockholders, which is to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K.

ELECTRO-OPTICAL SCIENCES, INC.
2005 FORM 10-K ANNUAL REPORT

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This Annual report on Form 10-K, including the sections labeled Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that you should read in conjunction with the financial statements and notes to financial statements that we have included elsewhere in this report. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. We generally identify these statements by words or phrases such as "believe," "anticipate," "expect," "intend," "plan," "will," "may," "should," "estimate," "predict," "potential," "continue," or the negative of such terms or other similar expressions. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements, and you should not place undue reliance on these statements. Factors that might cause such a difference include those discussed below under the heading "Risk Factors," as well as those discussed elsewhere in this Annual Report on Form 10-K. We disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the period covered by this report or otherwise.

Item 1. 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 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 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®.

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 562 suspicious pigmented skin lesions, using our most advanced system, MelaFind® missed a single melanoma in situ, and study dermatologists, who are skin cancer experts, missed an invasive melanoma. Further, the specificity of MelaFind® was 45.1%, compared to study dermatologists 20.0% ($p<0.0001$).

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 (non-melanoma 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 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 and Medicaid Services (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.

In 2005, we initiated an effort to refine the MelaFind® hardware with ASKION (Gera, Germany), which specializes in precision optics. We recently commenced delivery of MelaFind® systems to the field for beta testing. Following beta testing and additional refinements, as required, we expect to have new systems available in order to start the pivotal trial in 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 275 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 several of 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.

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. We recently commenced delivery of MelaFind® systems to the field for beta testing. Following beta testing and additional refinements, as required, we expect to have new systems available in order to start the pivotal trial in 2006.

Along with hardware development efforts, we have also developed, tested, and continue to refine the software components of the system, including lesion quality control 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.

Current Results of Training Studies and Blinded Tests

The following data were presented at the 2006 American Academy of Dermatology meeting in March 2006. These represent the most current results of the MelaFind® system. The current version of the MelaFind® classifier was trained on a set of 2,265 lesions including 221 melanomas, 87 high grade dysplastic nevi, and 1,957 other pigmented skin lesions. Following testing on the training set, it was then tested on the largest blinded series that we have performed to date – 562 lesions including 54 melanomas, 22 high grade dysplastic nevi, and 486 other pigmented skin lesions. The following table summarizes the results of the tests on the training and blinded data sets.

February 2006 — Training Study and Blinded Test Results

	Training	Blinded test	
	MelaFind®	MelaFind®	Study Dermatologists
Sensitivity	100%	Missed 1 in situ Melanoma	Missed 1 invasive Melanoma
Specificity	50.7%	45.1%	20.0%
		($p < 0.0001$)	
Over-Biopsy Ratio	4.4:1	5:1	7.3:1

The study dermatologists, who are experts in the detection of skin cancer, missed an invasive melanoma, indicating that the lesion was not suspicious for melanoma; the lesion was biopsied due to patient concern. MelaFind® missed one melanoma in situ. The specificity of MelaFind® was statistically significantly superior to that of study dermatologists ($p < 0.0001$). The over biopsy ratio, that is, the ratio of false positive interpretations to true positive interpretations, is higher for study dermatologists than for MelaFind®.

In a separate reader study of small lesions derived from the training and blinded data sets, above, the diagnostic performance of MelaFind® was compared with that of nine independent expert dermoscopists. This study was performed on 99 small lesions (49 melanomas and 50 non-melanomas), defined as lesions ranging from 2mm to 6mm in diameter. The following table demonstrates the performance (sensitivity and specificity) of the nine readers and MelaFind®. The doctors' impression of whether a lesion is a melanoma or not a melanoma on dermoscopic grounds is assessed by asking the question, "Is this a melanoma." Whether a lesion is sufficiently suspicious to warrant biopsy is assessed by asking the question, "Would you biopsy this lesion to rule-out melanoma?" MelaFind® answers both questions the same. The MelaFind® results compare quite favorably to the dermoscopists on these small, difficult to differentiate lesions.

	Is this a melanoma?	**Would you biopsy this lesion to rule-out melanoma?**
	Sensitivity / Specificity	Sensitivity / Specificity
Expert Dermatologists	38.78% / 82.32%	70.61% / 48.89%
MelaFind®	Sensitivity – 98% / Specificity – 44%	

In another study of 68 lesions derived from the training and blinded data sets, above, the ABCD (asymmetry, border irregularity, color variation, and diameter) criteria were assessed by two expert readers who pioneered the use of the ABCD criteria, and MelaFind®. The 68 lesions included 14 melanomas, 4 high grade dysplastic nevi, and 50 other lesions. The concordance of the ABCD criteria between MelaFind® and Reader 1 was 51.5% (A), 61.8% (B), 79.4% (C), and 83.8% (D); for Reader 2 and MelaFind®, the concordance was 57.4% (A), 57.4% (B), 80.9% (C), and 81.3% (D). There is appreciable but not complete overlap between the sets of lesions identified as being at risk for melanoma by clinical ABCD by expert dermatologists compared with quantitative ABCD using MelaFind®. The study further demonstrated that quantitative ABCD characteristics have very high sensitivity to melanoma.

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 derived from blinded tests utilizing pre-commercialization hardware systems with the most advanced software and MelaFind® classifiers will be equivalent or superior to the results obtained to date using the prototype systems and developmental software. We believe that the results of the pivotal study, which will utilize the optimized hardware and software, will 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 a 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.

An article published in 2005 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 (benign lesions derived from skin cells called Keratinocytes) 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.

Another article published in November 2005 describes the results of a study conducted using the SolarScan system developed by PolarTechnics, Ltd. The sensitivity and specificity of SolarScan on a training set of 1,644 melanocytic lesions (skin lesions derived from skin cells called melanocytes), including 260 melanomas was 90% and 61%, respectively. In a blinded study of 786 melanoncytic lesions including 122 melanomas, the sensitivity and specificity of SolarScan was 91% and 65%, respectively. In a reader study of 78 melanocytic lesions including 13 melanomas, the sensitivity and specificity of SolarScan was 85% and 65%, respectively, compared to the sensitivity and specificity of skin cancer experts (90% and 59%, respectively) and dermatologists (81% and 60%, respectively). SolarScan did not perform well on non-melanocytic lesions; for example, only 13% of seborrheic keratoses were successfully classified. We believe that since SolarScan is intended for melanocytic lesions only, its use is limited to expert dermatologists. Further, we believe that a sensitivity in the range of 90% would not gain market approval.

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 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 recently commenced delivery of MelaFind® systems to the field for beta testing. Following beta testing and additional refinements, as required, we expect to have new systems available in order to start the pivotal trial in 2006.

In March 2005, we were 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 and we are currently working on five-step versions. The classifiers have been trained on 221 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 275 melanomas, which are available for classifier training.

We have engaged a consultant 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 a 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 Food, Drug, and Cosmetic Act (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 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). 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 Investigational Device Exemption (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 (IRBs) 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 the US Department of Health and Human Services (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. The Health Insurance Portability and Accountability Act of 1996 (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 December 31, 2005, we had 28 full-time and 2 part-time employees, of whom 14 were engaged in research and development (including clinical and regulatory affairs), 7 in production (including document control and quality assurance) and 9 in marketing, sales and administrative activities. We believe that our relationship with our employees is good.

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.

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 contained in this report. 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 we will not have adequate financial or other resources to achieve significant commercialization of MelaFind®;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost; and
- rapid technological change may make our technology and products obsolete.

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 assisting in the diagnosis of almost all pigmented melanomas (other than those on palms, soles of the feet, in or near the eye, and inaccessible areas such as the edge of the nose). The final MelaFind® lesion classifier may 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 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 275 melanoma lesions are in the training database. The current classifier has been trained on 221 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 the sale of our equity securities, and have devoted substantially all of our resources to research and development relating to MelaFind®. Our net loss for the twelve months ended December 31, 2005 was $6.7 million, and as of December 31, 2005, we had an accumulated deficit of approximately $20.6 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, we expect that our general and administrative expenses will increase due to the additional operational and regulatory responsibilities applicable to public companies. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

We do not know of any product possessing the diagnostic assistance capabilities of MelaFind®. We believe that electro-optical products designed to enhance the visualization and analysis of potential melanomas have been approved or are under development by: Welch Allyn, Inc.; Heine Optotechnik; 3Gen, LLC; Derma Medical Systems, Inc.; Medical High Technologies S.p.A.; ZN Vision Technologies AG; Polartechnics, Ltd.; Astron Clinica, Ltd.; 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, including molecular imaging in which tagged antibodies search for cancer cell antigens, 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 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 increases 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.

Our operations have consumed substantial amounts of cash for each of the last six years. We currently believe that our available cash, cash equivalents and marketable securities, including the proceeds from our recently completed initial public offering, will be sufficient to fund our anticipated levels of operations through mid 2007. However, our business or operations may change in a manner that would consume available resources more rapidly than we anticipate. 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 third-party manufacturing capacity. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, material procurement, problems with production yields, and quality control and assurance. Developing commercial-scale manufacturing facilities that meet FDA requirements would require the investment of substantial additional funds and the hiring and retaining of additional management and technical personnel who have the necessary manufacturing experience.

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

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

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

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

Our manufacturing efforts currently rely on 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 Carl Zeiss Jena GmbH (Zeiss) for lens objective assemblies, on ASKION GmbH (ASKION) for the main subassembly and on Fairchild Semiconductor Corp., Panasonic Corp., Roithner-Laser Vienna, CompServ 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 procure their raw material on time, failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- suppliers may make errors in manufacturing components that could negatively 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 also entered into a production agreement 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 have entered into a confidentiality agreement and a development agreement with Carl Zeiss Jena GmbH for lens objective assemblies, and we intend to enter into a contract for the commercial production of lenses. These lenses are currently assembled by ASKION 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 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 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 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 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 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, Gerald Wagner, Ph.D., our Acting Chief Operating 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. 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 fair value of the options. In May 2005, we 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. We recorded in the fourth quarter of 2005 a charge to operations in the amount of $544,000 with respect to these options based upon the initial public offering price of $5.00 per share. We have also granted options that vest upon attainment of development milestones. Upon the attainment of each of the relevant development milestones there could be a significant compensation charge based on the fair value of such options. .

If we fail to maintain the adequacy of our internal controls, our ability to provide accurate financial statements could be impaired and any failure to maintain our internal controls 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 our Common Stock

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

We only recently completed our initial public offering. Prior to our initial public offering, there was no public market for our common stock. An active public market for our common stock may not continue to develop or be sustained. 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.

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. 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.

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

As of February 28, 2006, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates in the aggregate, beneficially owned approximately 46% of our outstanding common stock. 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 significantly. At February 28, 2006, we had 10,865,917 shares of common stock outstanding. All of the shares offered in our initial public offering completed on November 2, 2005 are freely tradeable without restriction or further registration under the federal securities laws, unless purchased by our affiliates or subject to a lock-up agreement. As of February 28, 2006, 4,191,671 shares of our common stock were subject to lock-up agreements that have been entered into by certain of our stockholders. These lock-up agreements expire on July 24, 2006. We estimate that all of the 6,523,164 shares of our common stock outstanding prior to our initial public offering not previously eligible for sale pursuant to Rule 144(k) will become available for sale under Rule 144(k) beginning October 27, 2006, except for approximately 525,534 shares held by our affiliates which will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144.

On or before July 28, 2006, 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 December 31, 2005, 1,115,415 shares were subject to outstanding options, of which 572,607 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.

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

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

- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;

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

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

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

Item 2. ***Properties***

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 items.

Item 3. ***Legal Proceedings***

We are not currently subject to any material legal proceedings, nor, to our knowledge, is any material legal proceeding threatened against us. From time to time, we may be a party to certain legal proceedings, incidental to the normal course of our business. While the outcome of these legal proceedings cannot be predicted with certainty, we do not expect that these proceedings will have a material effect upon our financial condition or results of operations.

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the fourth quarter of fiscal year 2005.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been traded on the NASDAQ Capital Market since October 28, 2005 under the symbol MELA. Prior to such time, there was no public market for our common stock. The following table sets forth the range of the high and low intraday prices for the period October 28, 2005 through December 31, 2005 as reported by the NASDAQ Capital Market:

Fiscal Year Ended December 31, 2005	High	Low
October 28, 2005 - December 31, 2005	$ 8.68	$ 5.00

As of February 28, 2006, there were approximately 230 holders of record of our common stock. This number does not include the number of persons whose shares are in nominee or in "street name" accounts through brokers.

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.

Securities Authorized For Issuance Under Equity Compensation Plans

The information required by this Item concerning the Company's equity compensation plans is discussed in Note 1-Principal Business Activities and Summary of Significant Accounting Policies —Deferred Compensation, Note 10-Stock Options and Warrants, and Note 15-Subsequent Events to the financial statements contained in Part II Item 8 of this annual report.

Use of Proceeds From Registered Securities

On October 28, 2005, the Company completed an initial public offering. The Company issued 4,000,000 shares of common stock on October 28, 2005 and 262,300 shares of common stock on November 15, 2005, both issuances at $5.00 per share. After deducting underwriting discounts and expenses and offering-related expenses, the initial public offering resulted in net proceeds to the Company of $17,687,000. A summary of the terms of the initial public offering can be found in the Company's registration statement on Form S-1, as amended (File No. 333-125517), which was declared effective by the Securities and Exchange Commission on October 28, 2005.

No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) and person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds have been invested in investment grade securities and money market accounts.

We are using, and intend to continue to use, these proceeds for research and development activities including clinical trials, development of our sales and marketing capabilities and general corporate

purposes including general and administrative expenses, as described in the use of proceeds section of our final prospectus filed with the SEC pursuant to Rule 424(b) (4) on October 28, 2005.

Item 6. Selected Financial Data

The following table sets forth selected financial data for our Company. The financial information for the years ended December 31, 2003, 2004 and 2005 and as of December 31, 2004 and 2005, has been derived from our audited financial statements and related notes appearing in Part II Item 8 of this report and should be read together with such financial statements and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section appearing in Part II Item 7 of this report. The financial information for the years ended December 31, 2001 and 2002 and as of December 31, 2001, 2002, and 2003, has been derived from our audited financial statements not included in this report. The historical results are not necessarily indicative of results of any future periods.

(in thousands, except share and per share data)

	Year ended December 31,				
	2001	2002	2003	2004	2005
Statements of Operations Data:					
Revenue from grants	$ 290	$ 547	$ —	$ —	$ —
Cost of grant revenue	193	564	—	—	—
General and administrative expenses	2,563	511	1,034	1,234	2,636
Research and development	144	404	828	1,892	3,822
Operating loss from continuing operations	(2,610)	(932)	(1,862)	(3,126)	(6,458)
Interest (income)/expense	(85)	8	76	67	(174)
Loss from continuing operations	(2,525)	(940)	(1,938)	(3,193)	(6,284)
Loss from discontinued operations	(343)	(201)	(12)	(426)	(442)
Net loss	(2,868)	(1,141)	(1,950)	(3,619)	(6,726)
Preferred stock deemed dividends	(213)	(214)	(322)	(676)	(1,199)
Preferred stock accretion	(180)	(180)	(25)	(258)	(1,077)
Stock distribution of preferred Series B shares	—	—	(102)	—	—
Net loss attributable to common stockholders	$ (3,261)	$ (1,535)	$ (2,399)	$ (4,553)	$ (9,002)
Net loss per share, basic and diluted:					
Continuing operations	$ (1.90)	$ (0.87)	$ (1.48)	$ (2.34)	$ (2.44)
Discontinued operations	(0.23)	(0.13)	(0.01)	(0.24)	(0.13)
Basic and diluted net loss per common share	$ (2.13)	$ (1.00)	$ (1.49)	$ (2.58)	$ (2.57)
Basic and diluted weighted average number of shares outstanding	1,534,760	1,534,760	1,614,897	1,766,608	3,508,835

(in thousands, except share and per share data)

	As of December 31,				
	2001	2002	2003	2004	2005
Balance Sheet Data:					
Total current assets	$ 867	$ 111	$ 217	$ 6,813	$ 18,873
Total assets	1,131	344	432	7,096	19,166
Total liabilities	247	529	650	691	916
Redeemable convertible preferred stock	2,155	2,244	4,067	9,955	—
Accumulated deficit	(7,197)	(8,518)	(10,288)	(13,907)	(20,633)
Total stockholders' equity/(deficiency)	(3,408)	(4,657)	(4,285)	(3,550)	18,249

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward looking statements, which involve risks and uncertainties. Our actual results could differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth above under the caption "Business-Risk Factors". You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements for the year ended December 31, 2005 and the related notes appearing in Part II Item 8 of this report.

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 pivotal 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 December 31, 2005, we had an accumulated deficit of $20.6 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. On October 28, 2005, the Company completed an initial public offering. The company issued 4,000,000 shares of common stock on October 28, 2005 and 262,300 shares of common stock on November 15, 2005, both issuances at $5.00 per share. After deducting underwriting discounts and expenses and offering related expenses, the initial public offering resulted in net proceeds to the Company of approximately $17.7 million. 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 for the year ended December 31, 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 December 31, 2005, we had available net operating loss carryforwards for federal income tax reporting purposes of approximately $12.2 million and $18.9 million, respectively. The

net operating loss carryforwards 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 included in this report, 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 December 31, 2004 consisted of revenues that were billed or paid in advance of the shipment of the product.

We currently do not have any products approved for sale.

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 could have a material effect on our financial statements in future accounting periods.

Prior to October 28, 2005, our common stock had not been publicly traded. As a result, the determination of the fair value of our common stock involved 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. Since our initial public offering, the fair value of stock-based compensation has been based on the price of our common stock on the measurement date.

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 our initial public offering. In

the fourth quarter of 2005, the Company recorded a charge to operations in the amount of $544,000 with respect to these options based upon the initial public offering price of $5.00 per share.

We have also granted to certain employees stock options that vest with the attainment of development milestones. Upon the attainment of the relevant development milestones, there could be a significant compensation charge based on the fair value of such options.

Upon the closing of the initial public offering, the Company issued to Gerald Wagner, Ph.D., Acting Chief Operating Officer and a member of the Company's Board of Directors, pursuant to a consulting agreement dated June 1, 2005, an option to purchase 50,000 shares of common stock with an exercise price equal to the initial public offering price of $5.00 per share. The fair value of these options was based on the Black-Scholes option-pricing model and the Company recognized compensation expense of $138,000 during the year ended December 31, 2005, as these options vested immediately. On March 24, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D. to be effective as of April 1, 2006. In connection with his ongoing engagement as a consultant, Dr. Wagner received a stock option grant of 50,000 shares of the Company's common stock which vests in full immediately upon commencement of the pivotal trial for MelaFind® (refer to Note 15 Subsequent Events for further details). In addition, on March 24, 2006, Dr. Wagner received another stock option grant of 49,500 shares of the Company's common stock which vests immediately. The exercise price for these two stock option grants is the closing price per share of the Company's common stock on the option grant date and the compensation charge to operations will be based on the fair value of such options.

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 .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. This is done as of each balance sheet date in our financial statements.

Results of Operations (in thousands)

Year Ended December 31, 2005 Compared to Year Ended December 31, 2004

Research and Development Expense. Research and development expense increased by $1,930 to $3,822 for the year ended December 31, 2005, from $1,892 for the year ended December 31, 2004. Of this increase, $494 was attributable to higher personnel and personnel related costs as we increased headcount to support our research and development programs, and higher outside product development and research consulting fees in the amount of $882 and $494 respectively, which relates to the development of our MelaFind® product. In addition, regulatory expense increased by $60 which represents actions taken by the Company to fully comply with FDA quality system regulations. For the year ended December 31, 2005 research and development costs were approximately 59% of total operating expenses. 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 expense increased by $1,402 to $2,636 for the year ended December 31, 2005 from $1,234 for the year ended December 31, 2004. The change was due to higher personnel and personnel related costs of $291 associated with the addition of key management positions, and $392 related to rent, utilities and moving expenses associated with an office expansion and a lease renewal. The increase in share-based compensation of $465 is principally attributable to the immediate vesting of 125,000 stock options upon completion of the initial public

offering. In addition, information technology consulting fees and the higher professional services cost associated with being a public company contributed to $233 of the overall increase. For the year ended December 31, 2005, general and administrative expenses were approximately 41% 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, 2005 was ($174) compared to $67 for the corresponding period in 2004. The increase in income for the for the year ended December 31,2005 was due to the higher average cash, cash equivalents and marketable securities balance compared to the prior year period. The interest expense for the year ended December 31, 2004 was principally related 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 related 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..

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.

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.

Liquidity and Capital Resources (in thousands)

From inception, we have financed our operations primarily through the use of working capital from the sale 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 equipment leases, financing loans or other debt instruments. As of December 31, 2005, we had $18,505 in cash, cash equivalents and marketable securities as compared to $6,703 at December 31, 2004, an increase of $11,802. The increase resulted primarily from the net proceeds of $17,687 from the Company's initial public offering, partially offset by cash used in operating activities. Our cash and cash equivalents at December 31, 2005 are liquid investments with a maturity of three months or less and consist of investments in money market funds with a commercial bank.

Cash Flows from Operating Activities. Net cash used in operations was $5,865 for the year ended December 31, 2005. For the years ended December 31, 2003 and 2004 the net cash used in operations was $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 noncash compensation, depreciation and other changes in operating assets and liabilities.

Cash Flows from Investing Activities. Net cash provided by our investing activities was $6,502 for the year ended December 31, 2005 principally relating to the redemption of marketable securities. For the years ended December 31, 2003 and 2004 the net cash used in investing activities was $8 and $6,677 respectively. The cash used in investing activities for the year 2004 was principally related to the purchase of marketable securities and equipment from the proceeds of our private placement financings.

Cash Flows from Financing Activities. Net cash provided by financing activities was $17,760 for the year ended December 31, 2005 and reflects the net proceeds received from the Company's initial public offering. For the years ended December 31, 2003 and 2004 the net cash flows provided by financing activities were, $1,816 and $9,733 respectively. For these periods, financing cash flows reflected the proceeds from the issuance of common stock, preferred stock and notes payable.

Operating Capital and Capital Expenditure Requirements

We face certain risks and uncertainties, which are present in many emerging medical device companies. At December 31, 2005, we had an accumulated deficit of $20.6 million. 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 our recently completed initial public offering, including our current cash and cash equivalents 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 our recently completed initial public 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, 2005 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	$909	$204	$600	$105	—
Total	$909	$204	$600	$105	—

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 our financial statements and the related notes to our financial statements included in this report.

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.

Recent Accounting Developments

On December 16, 2004 the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). This Statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements and establishes fair value as the measurement objective in accounting for all share-based payment arrangements. On March 29, 2005, the SEC issued Staff Accounting Bulletin No. 107, *Stock-Based Payment*, which summarizes the views of the staff regarding the interaction between SFAS 123R and certain SEC rules and regulations, and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS 123R was originally effective as of the beginning of the first interim or annual reporting period after June 15, 2005. However, on April 14, 2005 the SEC announced a new rule that amended the effective date for SFAS 123R. The new rule allows companies to implement SFAS 123R at the beginning of their next fiscal year, instead of the next reporting period beginning after June 15, 2005. As such, we will adopt SFAS 123R as of the beginning of the first quarter of 2006. 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 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 as it relates to existing option plans could have a material effect on our financial statements.

Item 7A.Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk at December 31, 2005 is confined to our cash and cash equivalents. We invest in high credit quality financial instruments; primarily money market funds with an original maturity of three months or less at the date of acquisition. 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. In January 2006, the Company invested $17,250,000 in high credit quality available-for-sale marketable debt securities with a weighted average maturity not to exceed twelve months. There has been no material change to our market risk since December 31, 2005.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying balance sheets of Electro-Optical Sciences, Inc. as of December 31, 2004 and 2005, and the related statements of operations, stockholders' equity/(deficiency), and cash flows for each of the years in the three-year period ended December 31, 2005. 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 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

/s/ Eisner, LLP

New York, New York
March 17, 2006, except as to
the second paragraph
of Note 15, the date
of which is March 24, 2006

ELECTRO-OPTICAL SCIENCES, INC.

BALANCE SHEETS

	December 31, 2004	December 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 108,705	$ 18,505,030
Marketable securities	6,594,751	—
Accounts receivable, net	7,128	—
Inventories	69,755	—
Prepaid expenses and other current assets	32,844	210,940
Assets held for sale	—	156,677
Total Current Assets	6,813,183	18,872,647
Property and equipment, net	89,306	175,369
Patents and trademarks, net	163,459	84,052
Other assets	30,201	33,612
Total Assets	$ 7,096,149	$ 19,165,680
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current Liabilities:		
Accounts payable (includes related parties of $2,000 as of December 31, 2004, and $11,263 as of December 31, 2005)	$ 338,821	$ 329,462
Accrued expenses (includes related parties of $15,000 as of December 31, 2005)	228,583	570,052
Deferred revenues	106,335	—
Other current liabilities	17,284	16,828
Total Current Liabilities	691,023	916,342
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, 2004	2,244,147	—
Redeemable Preferred Stock Series C convertible 5,744,340 shares designated (liquidation preference $2.26 per share); issued and outstanding 5,414,779 shares at December 31, 2004	7,711,027	—
COMMITMENTS AND CONTINGENCIES (Note 6)		
Stockholders' Equity (Deficiency):		
Preferred stock — $.10 par value; authorized 16,936,704 shares as of December 31, 2004, and 10,000,000 shares as of December 31, 2005		
Series A Convertible Preferred Stock, 199,380 shares designated – (liquidation preference $5.00 per share); issued and outstanding 198,000 shares at December 31, 2004	972,311	—
Common stock — $0.001 par value; authorized 30,000,000 shares: issued and outstanding 1,809,758 shares at December 31, 2004 and 10,837,833 shares at December 31, 2005	1,810	10,838
Additional paid-in capital	9,611,094	38,934,420
Notes receivable for stock subscriptions	(69,000)	—
Deferred compensation	(159,300)	(62,610)
Accumulated deficit	(13,906,963)	(20,633,310)
Stockholders' Equity (Deficiency)	(3,550,048)	18,249,338
Total Liabilities and Stockholders' Equity (Deficiency)	$ 7,096,149	$ 19,165,680

See accompanying notes to the financial statements

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF OPERATIONS

	Year ended		
	December 31, 2003	**December 31, 2004**	**December 31, 2005**
Operating expenses:			
Research and development	$ 828,239	$ 1,891,551	$ 3,821,712
General and administrative	1,034,397	1,234,210	2,636,064
Operating loss from continuing operations	(1,862,636)	(3,125,761)	(6,457,776)
Interest income	(1,373)	(27,935)	(173,888)
Interest expense	76,923	94,976	—
	75,550	67,041	(173,888)
Loss from continuing operations	(1,938,186)	(3,192,802)	(6,283,888)
Loss from discontinued operations	(11,917)	(426,344)	(442,459)
Net loss	(1,950,103)	(3,619,146)	(6,726,347)
Less:			
Preferred stock deemed dividends	321,830	676,218	1,198,439
Preferred stock accretion	25,228	257,545	1,077,492
Stock distribution of preferred Series B shares	101,700	—	—
Net Loss Attributable to Common Stockholders	**$ (2,398,861)**	**$ (4,552,909)**	**$ (9,002,278)**
Net loss per common share, basic and diluted:			
Continuing operations	(1.48)	(2.34)	(2.44)
Discontinued operations	(0.01)	(0.24)	(0.13)
Basic and diluted net loss per common share	$ (1.49)	$ (2.58)	$ (2.57)
Basic and diluted weighted average number of common shares outstanding	1,614,897	1,766,608	3,508,835

See accompanying notes to the financial statements

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)
Years Ended December 31, 2003, 2004 and 2005

	Convertible Preferred Stock Series A		Common Stock		Additional Paid-in Capital	Notes Receivable	Deferred Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount					
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	198,000	$ 972,311	1,809,758	$ 1,810	$ 9,611,094	$ (69,000)	$ (159,300)	$ (13,906,963)	$ (3,550,048)

December 31, 2004									
Preferred stock accretion					(1,077,492)				(1,077,492)
Conversion of preferred stock in connection with the Initial Public Offering	(198,000)	(972,311)	3,398,105	3,398	12,001,578				11,032,665
Value of employee options vesting on attainment of milestone					479,000				479,000
Issuance of options to consultant					138,000				138,000
Exercise of option by non-employee directors			27,500	28	15,322				15,350
Exercise of options by former employees			23,361	23	23,359				23,382
Restricted stock award to employee			11,488	12	62,598		(62,610)		—
Retirement of note receivable						69,000			69,000
Amortization of deferred compensation							159,300		159,300
Warrants exchanged for common stock			1,305,321	1,305	(1,305)				—
Issuance of shares of common stock in connection with the Initial Public Offering (net of expenses)			4,262,300	4,262	17,682,266				17,686,528
Net loss								(6,726,347)	(6,726,347)
Balance at December 31, 2005	—	$ —	10,837,833	$ 10,838	$ 38,934,420	$ —	$ (62,610)	$ (20,633,310)	$ 18,249,338

See accompanying notes to the financial statements

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF CASH FLOWS

	Year ended		
	December 31, 2003	December 31, 2004	December 31, 2005
Cash flows from operating activities:			
Loss from continuing operations	$ (1,938,186)	$ (3,192,802)	$ (6,283,888)
Loss from discontinued operations	(11,917)	(426,344)	(442,459)
Net loss	(1,950,103)	(3,619,146)	(6,726,347)
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	30,987	35,860	49,098
Noncash compensation and amortization of deferred compensation	22,500	172,950	638,300
Common stock options and warrants issued for consulting fees	96,836	193,196	138,000
Retirement of stock subscription receivable for consulting services	—	—	34,500
Amortization of discount on marketable securities	—	(10,001)	(33,502)
Imputed interest expense attributable to preferred Series C	45,000	—	—
Imputed interest expense from bridge loan	—	80,000	—
Changes in operating assets and liabilities:			
Decrease in receivables	53,585	20,662	8,128
(Increase) decrease in inventories	(39,296)	3,110	(16,122)
Increase in prepaid expenses and other current assets	(3,464)	(36,211)	(181,507)
Increase (decrease) in accounts payable and accrued expenses	137,414	(7,676)	332,110
(Decrease) increase in deferred revenues	(57,300)	106,335	(106,335)
(Decrease) increase in other current liabilities	(21,879)	5,308	(456)
Net cash used in operating activities	(1,699,008)	(3,064,613)	(5,865,133)
Cash flows from investing activities:			
Patent costs	(5,986)	(3,166)	(5,316)
Purchases of property and equipment	(2,432)	(88,884)	(121,239)
(Purchase) sale of marketable securities	—	(6,584,750)	6,628,253
Net cash (used in) provided by investing activities	(8,418)	(6,676,800)	6,501,698
Cash flows from financing activities:			
Proceeds from Initial Public Offering	—	—	21,311,500
Expenses related to Initial Public Offering	—	—	(3,624,972)
Proceeds from issuance of Series C preferred stock	1,500,000	9,171,480	—
Expenses related to Series C preferred stock offering	(252,278)	(447,553)	—
Proceeds from (repayment of) notes payable stockholders	48,000	(48,000)	—
Proceeds from issuance of notes payable	520,000	920,000	—
Proceeds from sale of common stock	—	137,500	38,732
Payment for stock subscription receivable	—	—	34,500
Net cash provided by financing activities	1,815,722	9,733,427	17,759,760
Net (decrease) increase in cash and cash equivalents	108,296	(7,986)	18,396,325
Cash and cash equivalents at beginning of period	8,395	116,691	108,705
Cash and cash equivalents at end of period	$ 116,691	$ 108,705	$ 18,505,030
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	$ 25,228	$ 257,545	$ 1,077,492

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		
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)
(For the years ended December 31, 2005, 2004 and 2003)

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).

At December 31, 2005, the Company has an accumulated deficit of $20,633 and anticipates that it will continue to incur net losses for the foreseeable future in the development and commercialization of the Melafind® device. From inception, the Company has financed operations primarily through the sale of convertible preferred stock and subsequent to that sold common stock as part of an initial public offering on October 28, 2005. (Refer to Note 9, "Initial Public Offering of Common Stock," and Note 8, "Stockholders' Equity (Deficiency) and Redeemable Convertible Preferred Stock," for further details.) The Company faces certain risks and uncertainties, which are present in many emerging medical device companies regarding future profitability, ability to obtain future capital, protection of patents and property rights, competition, rapid technological change, government regulations, changing health care marketplace, recruiting and retaining key personnel, and third party manufacturing organizations.

Business Segments

Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures about Segments of an Enterprise and Related Information*, requires an enterprise to report segment information based on how management internally evaluates the operating performance of its business units (segments). The Company's operations are confined to one business segment: the design and development of MelaFind®.

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. Upon the completion of the Company's initial public offering on October 28, 2005, all of the company's redeemable convertible preferred stock was automatically converted into 3,398,105 shares of the Company's common stock and all related deemed but unpaid dividends on the redeemable convertible preferred stock were forfeited.

Reclassification

Certain short term liabilities previously classified as accounts payable at December 31, 2004 have been reclassified as accrued expenses to conform with the current year's presentation.

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. The carrying value of these instruments approximates fair value.

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 December 31, 2005 consisted of DIFOTI® related inventories and patents.

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®.

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. As of June 30, 2005, in connection with the discontinuance of its DIFOTI® product line, the Company established a reserve for warranty expense in accordance with the requirements of SFAS No. 5 "*Accounting for Contingencies*", since the Company believed it was probable that such discontinuance would lead to warranty claims. As of December 31, 2005, prior sales of approximately $75 were subject to possible warranty claims.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under this method, 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. 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,		
	2003	2004	2005
Net loss attributable to common stockholders, as reported	$ (2,399)	$ (4,553)	$ (9,002)
Add: stock-based employee compensation included in reported net loss, net of income tax effect	23	173	638
Deduct: stock-based employee compensation expense determined under fair-value-based method, net of related tax effect	(65)	(186)	(539)
Pro forma net loss	$ (2,441)	$ (4,566)	$ (8,903)
Basic and diluted loss per share, as reported	$ (1.49)	$ (2.58)	$ (2.57)
Basic and diluted loss per share, pro forma	$ (1.51)	$ (2.58)	$ (2.54)

The per share weighted-average fair value of stock options granted during 2003, 2004 and 2005 was $.34, $3.00, and $3.63, respectively, on the dates of grant using the Black-Scholes option-pricing model. The following weighted-average assumptions were used:

	December 31,		
	2003	2004	2005
Expected volatility	1%	60%	60%
Risk-free interest rate	4.52% to 5.43%	3.17% to 3.94%	4.39%
Expected option life (in years)	10	5	5
Expected dividend yield	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) 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*. 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 and restricted stock awards is measured at the measurement date for the respective grants, and reflected as a deduction from stockholders' equity. In connection with the grant of certain stock options to employees during the month of December, 2004, the Company recorded total deferred compensation of $159 representing the difference between the fair value of the common stock and the option exercise price at the date of grant. Compensation expense is recognized ratably over the vesting period or upon achievement of a business-related milestone. The Company recognized $23 and $159 of amortization of deferred compensation as compensation expense for the years ended December 31, 2004 and 2005 respectively. During 2005, the unvested portion of the aforementioned December 2004 stock options vested immediately upon completion of the Company's initial public offering. (Refer to Note 10 "Stock Options and Warrants" for further details.)

In addition, the Company issued a restricted stock award of 11,488 shares to an employee in December, 2005 at the closing market price of the Company's stock at the date of grant and compensation expense in the amount of $63 for this award will be recognized on a straight line basis over the nontransferable 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.

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. Potential common stock equivalents excluded consist of stock options, warrants and redeemable convertible preferred stock which are summarized as follows:

	Year Ended December 31,		
	2003	2004	2005
Common stock options	290,678	965,203	1,115,415
Warrants	369,993	2,758,923	298,280
Redeemable convertible preferred stock	1,144,277	3,398,105	—
Total	1,804,948	7,122,231	1,413,695

Recent Accounting Developments

On December 16, 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). This Statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements and establishes fair value as the measurement objective in accounting for all share-based payment arrangements. On March 29, 2005, the SEC issued Staff Accounting Bulletin

No. 107, *Stock-Based Payment*, which summarizes the views of the staff regarding the interaction between SFAS 123R and certain SEC rules and regulations, and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS 123R was originally effective as of the beginning of the first interim or annual reporting period after June 15, 2005. However, on April 14, 2005 the SEC announced a new rule that amended the effective date for SFAS 123R. The new rule allows companies to implement SFAS 123R at the beginning of their next fiscal year, instead of the next reporting period beginning after June 15, 2005. As such, the Company adopted SFAS 123R as of the beginning of the first quarter of 2006 and began expensing the cost of equity instruments awarded as part of the Employee Stock Incentive Plan over the requisite period related to such awards. The Company has elected to implement this new standard under the modified prospective application. Under the modified prospective application, the Company will expense the cost of new or modified awards over the requisite service period and the cost of previously granted unvested awards for the requisite service period remaining after December 31, 2005. In addition, upon the adoption of the 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 position or its results of operations will depend upon various factors including its future compensation strategy. The Company expects that the effect of applying this statement on its results of operations as it relates to existing option plans could have a material effect on its financial statements.

2. Marketable Securities:

The Company's investments mature within one year. All marketable securities held-to-maturity were redeemed or liquidated prior to December 31, 2005 at their approximate carrying values. The Company realized a loss of $3 on the proceeds from the sale of $6,628 of held-to-maturity securities during the year ended December 31, 2005. Investments in marketable securities are summarized as follows for the year ended December 31, 2004:

	December 31, 2004		
	Gross unrealized Loss	Fair value	Amortized Cost
Corporate commercial paper	$ —	$ 2,500	$ 2,500
Corporate debt	(10)	2,497	2,507
United States Treasury note	(8)	1,580	1,588
	$ (18)	$ 6,577	$ 6,595

In January 2006, the Company invested $17,250 in high credit quality available-for-sale marketable debt securities with a weighted average maturity not to exceed twelve months.

3. Property and Equipment:

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

	December 31,		
	2004	2005	Estimated useful life
Leasehold improvements	$ 32	$ 86	Lease Term
Laboratory and research equipment	119	131	5 years
Office furniture and equipment	135	190	5 years
	286	407	
Less accumulated depreciation and amortization	197	232	
	$ 89	$ 175	

Depreciation and amortization expense amounted to approximately $15, $18 and $34, for the years ended December 31, 2003, 2004 and 2005, respectively.

4. Patents:

Patents are shown in the accompanying balance sheets net of accumulated amortization of $101 and $115 at December 31, 2004 and 2005, respectively. 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, $18 and $15 for the years ended December 31, 2003, 2004 and 2005, respectively.

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

Year ended December 31,	
2006	$ 10
2007	10
2008	10
2009	10
2010	10
Thereafter	34
	$ 84

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,	
2006	$ 204
2007	213
2008	217
2009	170
2010	105
	$ 909

Rent expense charged to operations amounted to approximately $113, $110 and $202 for the years ended December 31, 2003, 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 and renewed automatically for 2006.

During January 2004, the Company amended its employment agreement with its former President and Chief Science and Technology Officer. The agreement was originally entered into in May 2003 with a three-year term. The amended agreement included a salary of $175 and provided for stock options and performance bonuses. As of May 31, 2005, a new consulting agreement was entered into with this former employee, which superceded the amended employment agreement (see Note 11).

The Company is not currently subject to any material legal proceedings, nor to management's knowledge is any material legal proceeding threatened against the Company.

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 $12, $25 and $35 for the years ended December 31, 2003, 2004 and 2005, respectively.

8. Stockholders' Equity (Deficiency) and Redeemable Preferred Stock:

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 consisted 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 and the accretion to redemption value for this amount for the years ended December 31, 2003, 2004 and 2005 is presented in the recorded accretion table below. 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 are shown as a reduction in stockholders' equity (deficiency) for the year ended December 31, 2004. The notes bear interest at 3.06% and are due June 20, 2008. Interest income amounted to approximately $2 and $1 for the years ended December 31, 2004 and 2003, respectively. During the month of 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 $2,643. Costs of the Series C private placement amounted to approximately $448 and the accretion to redemption value for this amount for the years ended December 31, 2003, 2004 and 2005 is presented in the recorded accretion table below.

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 10. The Company recorded a beneficial conversion feature of $1,465.

The following table summarizes the recorded accretion to redemption value for the Series C for the years ended December 31, 2003, 2004 and 2005:

	Total Amount	Accretion period in months	Year ended December 31,		
			2003	2004	2005
June 2003 Series C financing costs	$ 252	60	$ 25	$ 51	$ 42
Oct. 2004 Series C financing costs	448	44		20	102
Value of Series C warrants	2,643	44		120	601
Beneficial Conversion — Series C	1,465	44	—	67	333
Total	$ 4,808		$ 25	$ 258	$ 1,078

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. Upon the completion of the Company's initial public offering on October 28, 2005, all of the company's preferred stock converted to common stock and all related deemed dividends were forfeited.

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.

Balance at December 31, 2003	$ 1,823
Issuance of Series C preferred stock in 2004, less associated costs of $448, 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

9. Initial Public Offering of Common Stock

On October 28, 2005, the Company completed an initial public offering. The company issued 4,000,000 shares of common stock on October 28, 2005 and 262,300 shares of common stock on November 15, 2005, both issuances at $5.00 per share. After deducting underwriting discounts and expenses and offering-related expenses, the initial public offering resulted in net proceeds to the Company of approximately $17,687. In connection with the initial public offering, all of the outstanding shares of the Company's redeemable convertible preferred stock were automatically converted into 3,398,105 shares of the Company's common stock. A summary of the terms of the initial public offering can be found in the Company's registration statement on Form S-1, as amended (File No. 33-125517), which was declared effective by the Securities and Exchange Commission on October 28, 2005.

10. Stock Options and Warrants:

Warrants

During 2005, the Company issued 1,305,321 shares of common stock in exchange for 2,610,643 outstanding warrants (a conversion ratio of one share of common stock for two warrants). The Company recorded this transaction as an exchange of equity instruments at fair value which had 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%.

The warrants outstanding at December 31, 2005 include a 5 year warrant to purchase 75,000 shares of common stock at an exercise price of $7.00 per share issued to one of the Company's consultants in 2004 and a 7 year warrant to purchase 73,280 shares of Series C preferred stock at an exercise price of $4.52 per share issued in connection with the sale of Series C redeemable convertible preferred stock. Upon completion of the Company's initial public offering on October 28, 2005, the Series C preferred stock warrants became exercisable for an aggregate of 73,280 shares of the Company's common stock. Additionally, in connection with the Company's initial public offering which closed on November 2, 2005, the Company issued 150,000 warrants to the underwriters to purchase common stock at $6.25 per share. The warrants are exercisable commencing October 28, 2006 and have a five year term.

Stock Options

The Company has three stock option plans (the "Plans") which allow the board of directors to grant incentives to employees, directors, consultants and collaborating scientists in the form of incentive stock options, nonqualified stock options and restricted stock. At December 31, 2005, stock options to purchase 1,115,415 shares of common stock at exercise prices ranging from $.40 to $ 6.85 per share are outstanding and are exercisable at various dates through 2015. There are 798,907 shares available for future grant under the Company's stock option plans as of December 31, 2005.

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 62,500 of these options resulted in a charge to operations in the amount of $150 and $71 during the years ended December 31, 2004 and 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. The remaining 200,000 aforementioned stock options issued vest upon the attainment of certain milestones.

Stock option activity during the periods indicated is as follows:

	Number of shares	Weighted-average exercise price
Outstanding at January 1, 2003	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
Granted	212,780	2.43
Exercised	(50,881)	.76
Expired/Forfeited	(11,687)	4.85
Outstanding at December 31, 2005	1,115,415	$ .95
Options exercisable at December 31, 2005	572,607	$ 1.07

The following table summarizes information about stock options outstanding at December 31, 2005:

	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	804,811	3.7 years	$ .46	296,503	$ .46
$.47-$1.00	230,604	4.8 years	1.00	226,104	1.00
$1.01-$6.85	80,000	4.9 years	5.69	50,000	5.00
$.01-$6.85	1,115,415	4.4 years	$ .95	572,607	$ 1.07

As of December 31, 2005, of the total stock options outstanding, 508,308 of these options will vest upon the attainment of certain development milestones and will be charged to operations based on the fair value of such options.

The employment agreement with the President and Chief Executive Officer (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. In the fourth quarter 2005, the Company recorded a charge to operations in the amount of $544 with respect to these options based upon the initial public offering price of $5.00 per share.

Upon the closing of the initial public offering, the Company issued a member of the Company's Board of Directors pursuant to a consulting agreement an option to purchase 50,000 shares of common stock with an exercise price equal to the initial public offering price of $5.00. The fair value of these options was based on the Black-Scholes option-pricing model using the following assumptions: 60% volatility, expected

dividend yield of 0%, an expected life of 5 years and risk-free interest rate of 4.375% and the Company recognized compensation expense of $138 during the year ended December 31, 2005, as these options vested immediately.

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 of $48 in 2003, $22 in 2004, and $26 in 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 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. The Company accrued $10 for the year ended December 31, 2005 pursuant to this consulting 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, payable ratably over the course of the term, and a stock option grant to purchase 50,000 shares of the Company's common stock, which was granted immediately upon the completion of the Company's initial public offering at the public offering price of $5.00 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 in accordance with the agreement reached with FDA.

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 $12, $426 and $442 for the years ended December 31, 2003, 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 December 31, 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. Income Taxes:

There is no provision for income taxes because the Company has incurred losses. At December 31, 2005, the Company had net operating loss carryforwards of approximately $18,934 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 $4,883, and $7,574 at December 31, 2004 and 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, 2003, 2004, and 2005 amounted to $753, $1,440 and $2,691, respectively.

14. Quarterly Operating Results (Unaudited)

The following is a summary of operating results by quarter for the years ended December 31, 2005 and 2004:

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2005:				
Loss from continuing operations	$(1,114)	$(1,365)	$(1,371)	$(2,434)
Loss from discontinued operations	$ (129)	$ (201)	$ (72)	$ (40)
Net Loss	$(1,243)	$(1,566)	$(1,443)	$(2,474)
Net loss attributable to common stockholders	$(1,928)	$(2,247)	$(2,125)	$(2,702)
Basic and diluted net loss per share of common stock	$ (1.07)	$ (1.24)	$ (1.14)	$ (0.32)
2004:				
Loss from continuing operations	$ (689)	$ (725)	$ (626)	$(1,152)
Loss from discontinued operations	$ (81)	$ (21)	$ (120)	$ (205)
Net Loss	$ (770)	$ (746)	$ (746)	$(1,357)
Net loss attributable to common stockholders	$ (893)	$ (890)	$ (891)	$(1,878)
Basic and diluted net loss per share of common stock	$ (0.53)	$ (0.51)	$ (0.49)	$ (1.04)

15. Subsequent Events

In January 2006, the Company entered into an agreement with ASKION GmbH to produce and test commercial grade Melafind® hand-held imaging device systems. Under the agreement, ASKION is to produce up to forty Melafind® imaging devices for the Company to be utilized in the Company's pivotal trial which will be conducted at over twenty clinical study sites in the United States. The Company is required to make payments to ASKION upon the delivery of the forty separate Melafind® systems which commenced in February 2006 and is scheduled for completion in May 2006. The Company believes that the total payments to ASKION pursuant to this agreement will not exceed $1.0 million.

On March 24, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D., Acting Chief Operating Officer and a member of the Company's Board of Directors. The effective date of this amended and restated agreement is April 1, 2006. Under this amended consulting agreement, the Company agrees to pay Dr. Wagner the annual amount of $180,000 payable monthly over the term of the agreement. The agreement will end at the option of Dr. Wagner or the Company, at any time by providing thirty days prior written notice or immediately upon the mutual agreement of the Company and Dr. Wagner. In addition, in connection with his ongoing engagement as a consultant, Dr. Wagner received a stock option grant of 50,000 shares of the Company's common stock which vests in full immediately upon commencement of the pivotal trial for Melafind®. Also, on March 24, 2006, Dr. Wagner received another stock option grant of 49,500 shares of the Company's common stock which vests immediately. The exercise price for these two stock option grants is the closing price per share of the Company's common stock on the option grant date and the compensation charge to operations will be based on the fair value of such options.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Based on their evaluation as of December 31, 2005, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) were sufficiently effective to ensure that the information required to be disclosed by us in this annual report on Form 10-K was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-K.

Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors and Executive Officers of the Registrant

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders (the "Proxy Statement"), which is expected to be filed no later than 120 days after the end of our fiscal year ended December 31, 2005, and is incorporated in this report by reference.

Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Exhibits and Financial Statement Schedules:

(1) Financial Statements

See the “Index to Financial Statements” in Part II Item 8 of this report.

(2) Financial Statement Schedules

Not applicable.

(3) Exhibits

A list of exhibits required by Item 601 of Regulation S-K filed or incorporated by reference is found in the Exhibit Index immediately following Part IV of this report.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant. (1)
3.2	Third Amended and Restated Bylaws of the Registrant. (2)
4.1	Specimen Stock Certificate.(2)
4.2	Second Amended and Restated Investor's Rights Agreement dated as of October 26, 2004 by and among the Registrant and the parties listed therein. (3)
10.1*	Form of Indemnification Agreement for directors and executive officers. (2)
10.2*	1996 Stock Option Plan. (3)
10.3*	2003 Stock Incentive Plan, as amended. (3)
10.4*	2005 Stock Incentive Plan. (2)
10.5*	Employment Agreement dated as of January 5, 2004 between the Registrant and Joseph V. Gulfo. (3)
10.6	Consulting Agreement dated as of May 31, 2005 between the Registrant and Marek Elbaum. (3)
10.7	Lease Agreement dated as of December 16, 1998, by and between the Registrant and Bridge Street Properties LLC, for office space located at One Bridge Street, Irvington, New York. (3)
10.8	First Amendment to the Lease Agreement dated as of May 17, 2001 by and between the Registrant and Bridge Street Properties LLC. (3)
10.9	Second Amendment to the Lease Agreement dated as of June 19, 2003 by and between the Registrant and Bridge Street Properties LLC. (3)
10.10	Lease Agreement dated as of November 23, 2004, by and between the Registrant and Bridge Street Properties LLC, for office space located at 3 West Main Street, Irvington, New York. (3)
10.11*	Consulting Agreement dated as of June 1, 2005 between the Registrant and Gerald Wagner Consulting, LLC. (1)
10.12*	Consulting Agreement dated as of June 20, 2003 between the Registrant and Breaux Castleman, as amended. (1)
10.13	Consulting Agreement dated as of June 1, 2005 between the Registrant and Robert Friedman, M.D. (1)
10.14	Task Order Agreement dated as of July 13, 2005 between the Registrant and Battelle Memorial Institute. (2)
10.15	Third Amendment dated as of June 6, 2005, by and between the Registrant and Bridge Street Properties LLC, for office space located at 1 Bridge Street, Irvington, New York. (1)

Exhibit Number	Exhibit Title
10.16	Production Agreement between the Registrant and ASKION GmbH dated as of January 25, 2006. (4)
10.17#	Amended and Restated Consulting Agreement effective as of April 1, 2006 between the Registrant and Gerald Wagner Consulting LLC
21.1#	Subsidiaries of Registrant.
31.1#	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Indicates management compensatory plan, contract or arrangement

1 Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on July 15, 2005.

2 Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on August 8, 2005.

3 Incorporated by reference to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-125517), as filed on June 3, 2005.

4 Incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 31, 2006.

Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELECTRO-OPTICAL SCIENCES, INC.

Dated: March 29, 2006

By: /s/ Joseph V. Gulfo
Joseph V. Gulfo
President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Joseph V. Gulfo, M.D. **Joseph V. Gulfo, M.D.**	Director, President and Chief Executive Officer (Principal Executive Officer)	March 29, 2006
/s/ Karen Krumeich **Karen Krumeich**	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2006
/s/ Breaux Castleman **Breaux Castleman**	Chairman of the Board of Directors	March 29, 2006
/s/ Sidney Braginsky **Sidney Braginsky**	Director	March 29, 2006
/s/ George C. Chryssis **George C. Chryssis**	Director	March 29, 2006
/s/ Martin D. Cleary **Martin D. Cleary**	Director	March 29, 2006
/s/ Dan W. Lufkin **Dan W. Lufkin**	Director	March 29, 2006
/s/ Gerald Wagner, PhD. **Gerald Wagner, PhD.**	Director	March 29, 2006

EXHIBIT 10.17

AMENDED AND RESTATED CONSULTING AGREEMENT

This Amended and Restated Consulting Agreement is made as of April 1, 2006 (the "Effective Date"), between Electro-Optical Sciences, Inc, a Delaware corporation (the "**Company**") and Gerald Wagner Consulting LLC (the "**Consultan**t").

WHEREAS, the Consultant and the Company are parties to a certain Consulting Agreement dated as of June 1, 2005 (the "Prior Agreement"); and

WHEREAS, the parties to the Prior Agreement now wish to revise their relationship so as to provide for the provision of services of an anticipated longer duration period.

NOW THEREFORE, the parties agree as follows:

1. Services. The field of interest for consulting hereunder is the continued direction of the Company's MelaFind product development effort and the implementation of the manufacturing process once production of clinical trial prototypes becomes feasible.

The Consultant will make himself available in person at the Company's offices or other locations as agreed upon during the term of this Agreement, as reasonably requested by the Company.

2. Consideration. In consideration for the services provided by Consultant under the terms of this Agreement, Consultant shall be compensated as set forth below.

2.1 The Company will pay the Consultant the annual amount of one hundred eighty thousand dollars ($180,000.00), payable monthly over the term of this Agreement.

2.2 The Consultant acknowledges that, in connection with his continued engagement by the Company on March 24, 2006 he was granted non-qualified stock options to purchase 50,000 shares of the Company's common stock at fair market value.

2.3 Reasonable expenses of the Consultant incurred at the request of the Company (including travel expenses incurred in connection with Company-related business) will be reimbursed promptly by the Company, subject to customary verification, in accordance with the Company's standard expense reimbursement and travel policy.

3. Term. The term of this Agreement (the "Term") shall commence on the Effective Date of this Agreement and will end (a) at the option of Consultant or the Company, at any time by providing thirty (30) days' prior written notice to the other party (during which thirty (30) day period Consultant shall continue to perform its duties hereunder) or (b) immediately upon the mutual agreement of the Company and Consultant.

4. Certain Other Contracts.

4.1 The Consultant will not disclose to the Company any information that the Consultant is obligated to keep secret pursuant to an existing confidentiality agreement with a third party, and nothing in this Agreement will impose any obligation on the Consultant to the contrary.

4.2 The consulting work performed hereunder will not be conducted on time that is required to be devoted to any other third party. The Consultant shall not use the funding, resources and facilities of any other third party to perform consulting work hereunder and shall not perform the consulting work hereunder in any manner that would give any third party rights to the product of such work.

4.3 The Consultant has disclosed and, during the Term, will disclose to the Chief Executive Officer of the Company any conflicts between this Agreement and any other agreements binding the Consultant.

5. Exclusive Services during the Term. The Consultant agrees that during the Term of this Agreement he will not, exclusive of any research obligations to any third party, directly or indirectly, (i) provide any services to any other business or commercial entity engaged in the manufacture, development, marketing or sale of any medical device used in connection with the diagnosis of melanoma (the "**Field of Interest**"), (ii) participate in the formation of any business or commercial entity in the Field of Interest or (iii) solicit or hire away, or assist or facilitate the solicitation or hiring of, any employee or consultant of the Company.

6. Direction of Projects and Inventions to the Company. Subject to the Consultant's obligations and confidentiality obligations to third parties, during the Term of this Agreement, the Consultant will use his best efforts to disclose to the Chief Executive Officer of the Company, on a confidential basis, technology and product opportunities which come to the attention of the Consultant in the Field of Interest, and any invention, improvement, discovery, process, formula or method or other intellectual property relating to or useful in, the Field of Interest (collectively "New Discoveries"), whether or not patentable or copyrightable, to the extent the New Discoveries do not arise from any research undertaken by the Consultant as an employee of any third party.

7. Inventions Discovered by the Consultant While Performing Services Hereunder.

7.1 The Consultant will promptly and fully disclose to the Chief Executive Officer of the Company any invention, improvement, discovery, process, formula, technique, method, trade mark, trade secret, mask work, or other intellectual property, whether or not patentable, whether or not copyrightable (collectively, "Invention") made, conceived, developed, or first reduced to practice by the Consultant, either alone or jointly with others, while performing services hereunder. All such Inventions are work made for hire to the extent allowed by law and, in addition, Consultant hereby assigns to

the Company all of his right, title and interest in and to any such Inventions. The Consultant will execute any documents necessary to perfect the assignment of such Inventions to the Company and to enable the Company to apply for, obtain, and enforce patents or copyrights in any and all countries on such Inventions. The Consultant hereby irrevocably designates the Secretary of the Company as his agent and attorney-in-fact to execute and file any such document and to do all lawful acts necessary to apply for and obtain patents and copyrights, and to enforce the Company's rights under this paragraph. This Section 7 will survive the termination of this Agreement.

7.2 If any part of the Invention is based on, incorporates, or is an improvement or derivative of, or cannot be reasonably and fully made, used, reproduced, distributed and otherwise practiced or exploited without using, infringing or violating technology or intellectual property rights owned or licensed by Consultant and not assigned hereunder, Consultant hereby grants Company a perpetual, irrevocable, worldwide royalty-free, non-exclusive, right and license, with right to sublicense, to exploit and exercise all such technology and intellectual property rights in support of Company's exercise or exploitation of the Inventions, other work performed hereunder, or any assigned rights (including any modifications, improvements and derivatives of any of them).

8. Confidentiality.

8.1 The Consultant acknowledges that, during the course of performing his services hereunder, the Company will be disclosing information to the Consultant, and the Consultant will be developing information related to the Field of Interest, Inventions, projects, products, potential customers, personnel, business plans, and finances, as well as other commercially valuable information (collectively "Confidential Information"). The Consultant acknowledges that the Company's business is extremely competitive, dependent in part upon the maintenance of secrecy, and that any disclosure of the Confidential Information would result in serious harm to the Company.

8.2 The Consultant agrees that the Confidential Information will be used by the Consultant only in connection with consulting activities hereunder, and will not be used in any way that is detrimental to the Company.

8.3 The Consultant agrees not to disclose, directly or indirectly, the Confidential Information to any third person or entity, other than representatives or agents of the Company. The Consultant will treat all such information as confidential and proprietary property of the Company.

8.4 The term "Confidential Information" does not include information that was: (i) publicly known and made generally available in the public domain prior to the time of disclosure by the disclosing party; (ii) becomes publicly known and made generally available after disclosure by the disclosing party to the receiving party through no action or inaction of the receiving party; (iii) is already in the possession of the receiving party at the time of disclosure by the disclosing party as shown by the receiving party's files and records immediately prior to the time of disclosure; (iv) is obtained by

the receiving party from a third party without a breach of such third party's obligations of confidentiality; and (v) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as shown by documents and other competent evidence in the receiving party's possession.

8.5 The Consultant may disclose any Confidential Information that is required to be disclosed by law, government regulation or court order. If disclosure is required, the Consultant will give the Company advance notice so that the Company may seek a protective order or take other action reasonable in light of the circumstances.

8.6 Upon termination of this Agreement, the Consultant will promptly return to the Company all materials containing Confidential Information as well as data, records, reports and other property, furnished by the Company to the Consultant or produced by the Consultant in connection with services rendered hereunder, together with all copies of any of the foregoing. Notwithstanding such return, the Consultant shall continue to be bound by the terms of the confidentiality provisions contained in this Section 8 for a period of three years after the termination of this Agreement.

9. Use of Name. It is understood that the name of the Consultant and Consultant's affiliation with any third party will appear in disclosure documents required by securities laws, and in other regulatory and administrative filings in the ordinary course of the Company's business. The above-described uses will be deemed to be noncommercial uses. The name of the Consultant or any third party will not be used for any commercial purpose without the Consultant's consent.

10. No Conflict; Valid and Binding. The Consultant represents that neither the execution of this Agreement nor the performance of the Consultant's obligations under this Agreement will result in a violation or breach of any other agreement by which the Consultant is bound. The Company represents that this Agreement has been duly authorized and executed and is a valid and legally binding obligation of the Company, subject to no conflicting agreements.

11. Notices. Any notice provided under this Agreement shall be in writing and shall be deemed to have been effectively given (i) upon receipt when delivered personally, (ii) one day after sending when sent by private express mail service (such as Federal Express), or (iii) 5 days after sending when sent by regular mail to the following address:

In the case of the Company:

Electro-Optical Sciences, Inc
3 West Main Street, Suite 201
Irvington, NY 10553

In the case of the Consultant:

Gerald Wagner Consulting LLC
970 Route 9W
Upper Grandview, NY 10960

or to other such address as may have been designated by the Company or the Consultant by notice to the other given as provided herein.

12. Independent Contractor; Withholding. The Consultant will at all times be an independent contractor, and as such will not have authority to bind the Company. Consultant will not act as an agent nor shall he be deemed to be an employee of the Company for the purposes of any employee benefit program, unemployment benefits, or otherwise. The Consultant recognizes that no amount will be withheld from his compensation for payment of any federal, state, or local taxes and that the Consultant has sole responsibility to pay such taxes, if any, and file such returns as shall be required by applicable laws and regulations. Consultant shall not enter into any agreements or incur any obligations on behalf of the Company.

13. Assignment. Due to the personal nature of the services to be rendered by the Consultant, the Consultant may not assign this Agreement. The Company may assign all rights and liabilities under this Agreement to a subsidiary or an affiliate or to a successor to all or a substantial part of its business and assets without the consent of the Consultant. Subject to the foregoing, this Agreement will inure to the benefit of and be binding upon each of the heirs, assigns and successors of the respective parties.

14. Severability. If any provision of this Agreement shall be declared invalid, illegal or unenforceable, such provision shall be severed and the remaining provisions shall continue in full force and effect.

15. Remedies. The Consultant acknowledges that the Company would have no adequate remedy at law to enforce Sections 5, 7 and 8 hereof. In the event of a violation by the Consultant of such Sections, the Company shall have the right to obtain injunctive or other similar relief, as well as any other relevant damages, without the requirement of posting bond or other similar measures.

16. Governing Law; Entire Agreement; Amendment. This Agreement shall be governed by the laws of the State of New York applicable to agreements made and to be performed within such State, and represents the entire understanding of the parties with respect to the subject matter hereof. It supersedes the Prior Agreement except with respect to matters (payment for subsequent invoices, confidentiality, and the like) which by their nature should survive the termination of that agreement. It may only be amended in writing.

IN WITNESS WHEREOF, this Agreement may be executed in counterparts, each of which shall constitute an original and all of which together shall constitute one instrument, effective as of the date first above written.

Electro-Optical Sciences, Inc:

By: /s/ Joseph V. Gulfo
Joseph V. Gulfo, M.D. M.B.A.
President

Gerald Wagner Consulting LLC

By: /s/ Gerald Wagner
Gerald Wagner

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

The Registrant does not have any subsidiaries.

Exhibit 31.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934

I, Joseph V. Gulfo, certify that:

1. I have reviewed this report on Form 10-K of Electro-Optical Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operations of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Joseph V. Gulfo
Joseph V. Gulfo
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 29, 2006

Exhibit 31.2

CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934

I, Karen Krumeich, certify that:

1. I have reviewed this report on Form 10-K of Electro-Optical Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operations of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Karen Krumeich
Karen Krumeich
Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Date: March 29, 2006

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned officers of Electro-Optical Sciences, Inc.(the "Company") hereby certifies to his knowledge that the Company's annual report on Form 10-K for the period ended December 31, 2005 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo
JOSEPH V. GULFO
President and Chief Executive Officer
(Principal Executive Officer)

March 29, 2006

/s/ Karen Krumeich
KAREN KRUMEICH
Vice President & Chief Financial Officer
(Principal Accounting and Financial Officer)

March 29, 2006

*A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Electro-Optical Sciences, Inc. and will be retained by Electro-Optical Sciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This written statement accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and will not be incorporated by reference into any filing of Electro-Optical Sciences, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, irrespective of any general incorporation language contained in such filing.