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UNITED STATES 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, 2007

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:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common stock, $0.001 par value	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller Reporting company o

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 aggregate market value of the 12,649,338 shares of common stock held by non-affiliates of the registrant as of June 30, 2007 was $85,003,551 based on the last reported sale price of $6.72 per share on the Nasdaq Capital Market on June 30, 2007. (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 holding approximately 5.6% of the registrant's outstanding shares; such exclusion shall not be deemed to constitute an admission that any such person is an "affiliate" of the registrant. There were no shareholders holding at least 10% of the Company's common stock). The number of shares outstanding of the registrant's common stock as of February 28, 2008 was 15,401,882 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2008 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.

2007 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," "assuming," "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 section "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 light of multiple wavelengths 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; and
- our *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions.

We have entered into a binding Protocol Agreement with the 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. On October 12, 2006, we announced that the FDA had informed us that when submitted, the MelaFind® premarket approval, or PMA, application would receive expedited review. Expedited review means that upon filing a PMA with the FDA, it is placed at the beginning of the FDA's queue and receives additional review resources. While the expedited review could shorten the MelaFind® FDA approval process, we can give no assurances that this will be the case. The pivotal trial commenced in late January 2007 and was over two-thirds complete at the end of 2007. Upon obtaining premarket approval from the FDA, we plan to launch MelaFind® in the United States. If the pivotal trial and FDA approval process proceed as anticipated, management believes that PMA approval could come as early as the second half of 2008.

To date, we have not generated any revenues from MelaFind®.

Cancers of the skin have a higher incidence than all other cancers combined, and the rates are rising dramatically. Believed to be over 120,000 new cases of melanoma in 2007, a similar number of new cases is projected in 2008. Melanoma is responsible for approximately 75% 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 approximately 6,000 skin lesions from approximately 4,500 patients at over 30 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.

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®. On December 11, 2006 we announced that we had signed an exclusive sale and licensing agreement with KaVo Dental GmbH (KaVo), a leading dental equipment manufacturer and subsidiary of Danaher Corporation, to further develop and commercialize DIFOTI®. In accordance with the terms of the agreement, KaVo paid us an up-front sum and made a second payment to us in July 2007. If KaVo is successful in commercializing DIFOTI®, KaVo will pay us an annual royalty based on the number of systems sold per calendar year following commercial re-launch of DIFOTI®or a set minimum royalty payment, whichever is greater.

The Market Opportunity

Cancer of the skin (non-melanoma and melanoma skin cancers combined) is the most common of all cancers, with over 1.3 million projected cases annually, and is estimated to account for more than 50% of all cancers. Believed to be over 120,000 new cases of melanoma in 2007, a similar number of new cases is projected in 2008. There are three significant forms of skin cancer: basal cell, accounting for approximately 75% of skin cancer cases; squamous cell, totaling approximately 20% of skin cancer cases; and melanoma, which accounts for an estimated 4% of skin cancer cases, but is responsible for approximately 75% of all deaths from skin cancer. The American Cancer Society projects over 10,000 deaths annually from skin cancer. 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.

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®. The study commenced in late January 2007 and was over two-thirds complete as of the end of 2007. On October 12, 2006, we announced that the FDA had informed us that when submitted, the MelaFind® premarket approval, or PMA, application would receive expedited review. Expedited review means that upon filing a PMA with the FDA, it is placed at the beginning of the FDA's queue and receives additional review resources. While the expedited review could shorten the MelaFind® FDA approval process, we can give no assurances that this will be the case. Upon obtaining premarket approval from the FDA, we plan to launch MelaFind® in the United States. If the pivotal trial and FDA approval process proceed as anticipated, management believes that PMA approval could come as early as the second half of 2008.
- *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 eight 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 payer 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 payers for similar products. The value drivers in the model include the cost savings associated with early detection 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 national coverage decision from CMS may take

an additional 18 to 36 months following PMA approval, and obtaining a positive coverage decision from private payers, 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 and through negotiated payment arrangements with several third-party payers.

Additionally, our strategy includes the potential acquisition of complementary products and technologies in the dermatological diagnostic arena.

Limitations of Current Melanoma Diagnosis

Melanomas are mainly diagnosed by dermatologists and/or primary care physicians using visual clinical evaluation. This subjective interpretation relies on physician experience and skill. 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 hand-held imaging device that, in commercial use, will perform all diagnosis at the point of care. 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 generated in the physician's office containing considerable objective information about the lesion that is currently not available to doctors including 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 approximately 6,000 biopsied lesions from approximately 4,500 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. 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.

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 system were experienced, requiring further refinement of the system. 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 GmbH (Gera, Germany), which specializes in precision optics. ASKION has become an integral member of our MelaFind® development team and we expect to continue to work with ASKION for the foreseeable future. ASKION has produced MelaFind® systems for our pivotal clinical trials that began in late January 2007 and is currently building additional units and performing other additional developmental activities.

In August of 2006, the Company engaged Carl Zeiss Jena GmbH ("Zeiss") on usual commercial terms to build the lenses and assemblies that are being used in MelaFind®. In addition, Zeiss will provide certain

technical consulting for production scale-up and second generation MelaFind® system. We expanded this technical relationship with Zeiss during 2007 and expect to continue to work with Zeiss throughout 2008.

We reviewed our strategy with the FDA and obtained confirmation from the FDA that our plan to correct the technical issues by refining the hardware systems and to start the new pivotal trial to satisfy the Protocol Agreement was acceptable. In addition, in October 2006, the FDA informed us that when submitted, the MelaFind® PMA application would receive expedited review. Expedited review means that upon filing a PMA with the FDA, it is placed at the beginning of the FDA's queue and receives additional review resources. While the expedited review could shorten the MelaFind® FDA approval process, we can give no assurances that this will be the case. Upon obtaining premarket approval from the FDA, we plan to launch MelaFind® in the United States. If the pivotal trial and FDA approval process proceed as anticipated, management believes that PMA approval could come as early as the second half of 2008. 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 approximately 6,000 skin lesions from approximately 4,500 patients during the past five years at over 30 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 450 melanomas, including *in vivo* MelaFind® images and biopsy results, for MelaFind® software and *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 over 400 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* are 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 the 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 have now developed a pre-commercialization version for use in our pivotal clinical trial that began in late January 2007 and was over two-thirds complete at the end of 2007. 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 the second generation of hand-held imaging devices and purged the training database of lesion images acquired with 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 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 used to generate final, pre-commercialization hand-held imaging devices, which are being utilized in the pivotal study for PMA approval under the terms of the Protocol Agreement. We delivered MelaFind® systems to the field for beta testing in late 2006. Following beta testing and additional refinements in late 2006, we began our pivotal clinical trial in late January 2007 and at the conclusion of 2007, the study was over two-thirds complete.

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 American Academy of Dermatology meeting and are the most current published results of the MelaFind® system. 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.

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? Sensitivity / Specificity	Would you Biopsy this Lesion to Rule-Out Melanoma? 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 trial, 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 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, directly or indirectly, a focused sales, marketing, and distribution effort in North America. We plan to concentrate 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. While we are exploring potential partnership opportunities for the purpose of marketing and commercializing MelaFind®, at this time we have not yet established any such partnership arrangements.

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 payers 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, 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®. 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 payers.

In advance of obtaining a CPT code, we intend to extend our efforts to secure coverage by private payers and Medicare administrative contractors. Securing coverage first through private payers 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 payers 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 payers, 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 payers 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 overutilization 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 the second half of 2008, we are considering submitting an application for a new CPT code to the American Medical Association (AMA) CPT Editorial Panel in late 2009, and anticipate possible issuance of a new CPT code and positive national or regional Medicare coverage determinations in the first or second quarter of 2011. 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 payers, managed care organizations, and state Medicaid agencies. We expect to commence efforts to obtain positive coverage decisions from private payers, 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 payers, 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 payers, 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 request 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 payers 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 payers 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- change 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, High Medical Systems S.P.A., Vision Technologies AG (Germany), Polartechnics, Ltd. (Australia), Biomips Engineering (Italy). and Sci Base AB (Stockholm Sweden). 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. In addition, Sci Base AB is developing electrical impedance technology for melanoma detection.

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). Other imaging modalities, including molecular imaging in which tagged antibodies search for cancer cell antigens, and molecular and genetic screening tests. Molecular-based approaches are being investigated; Dermtech is exploring Messenger RNA analysis of surface cells for example.

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, 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 building the MelaFind® hand-held imaging devices and in designing methods to facilitate larger-scale manufacturing of both the pre-commercialization and commercial devices. For this crucial phase in development, we have contracted with ASKION, which specializes in precision optics. We have also contracted with Zeiss, an international optics house, to supply lenses to ASKION to be used in the hand-held clinical units.

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. The DIFOTI® inspectional findings were discussed in a subsequent meeting with the FDA on April 28, 2005. An onsite consultant was hired to address these deficiencies and structure a compliant Quality System for MelaFind®. During 2006 we worked to address the deficiencies noted in accordance with the agreement reached with the FDA. On May 18, 2006, the FDA re-audited the Company's facility for a follow-up inspection and audited our revised Quality System. No non-conformities or negative observations were reported to the Company. On December 5, 2006 we received correspondence from the FDA that reported "that all previous observations reported on the FDA-483 were corrected, and this firm no longer manufactures or distributes the DIFOTI® 2.0 dental imaging system." The Quality System implemented at EOS for MelaFind® Design and Development corrected the deficiencies observed by FDA inspection (March 2005), eliminated processes that were no longer in use (manufacturing at EOS) and implemented a streamlined FDA regulation compliant Design Control process for MelaFind®.

Research and Development Efforts

Our research and development efforts are currently focused on the execution of the pivotal trial, 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 and six-step versions. The classifiers have been trained on 221 melanomas to date, and our goal is to use over 6,000 pigmented skin lesions including approximately 450 melanomas for MelaFind® software and *Lesion Classifier* algorithm development and training. To date we have collected over 400 melanomas, which are available for classifier training.

Our R&D plan also includes further improvements such as faster and easier software downloads for future software versions.

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®.

We further intend to explore and 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 15 US patents with numerous foreign counterparts, of which eight US patents and two Australian patents relate to various aspects of melanoma detection. In addition, we have applied for five additional US patents and have filed certain foreign patent applications relating to melanoma detection, 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 MelaFind® intellectual property other than licenses granted in connection with the discontinuation of DIFOTI® operations (see 'Discontinued Business' and Note 10 to our Financial Statements.)

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 or 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 skinsurf.com.

The following table lists our US patents and patent applications relating to melanoma detection:

US Patents Relating to Melanoma Detection

Patent #	Title	Issued	Expiration
6,081,612	Systems and Methods for the Multispectral Imaging and Characterization of Skin Tissue	06/27/00	02/27/18
6,208,749	Systems and Methods for the Multispectral Imaging and Characterization of Skin Tissue	03/27/01	02/27/18
6,307,957	Multispectral Imaging and Characterization of Biological Tissue	10/23/01	02/27/20
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
7,102,672	Integrated CMOS Imaging Array & Dark Current Monitor	09/05/06	01/10/24
7,127,094	Method of Controlling Data Gathered at Remote Locations	10/24/06	03/11/25

Filed US Patent Relating to Melanoma Detection

Patent #	Title	Filed
n/a	Reducing noise in Digital Images	08/9/06
n/a	Quantitative Analysis of Skin Characteristics	03/2/07
n/a	Regulating use of a device to perform a procedure on a subject	06/12/07
n/a	Dermatology information	09/04/07
n/a	Characterizing a texture of an image	12/14/07

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 No. 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 No. 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 No. 6,710,947 describes a method for the economical assembly of the nine elements of the MelaFind® hand-held device's optical lens apparatus.

Patent No. 7,102,672 is a process that we may employ to compensate for the effect of temperature-dependent dark current on the images acquired by the MelaFind® hand-held probe, and Patent No. 7,127,094 is a series of methods for central control of the acquisition and processing of the image data acquired by MelaFind® probes located at remotes sites.

Our patent filed August 9, 2006 seeks to protect a novel method for reducing noise in digital images, which was invented and has been implemented as part of the calibration of all MelaFind® images. The March 2, 2007 filing protects a device for quantitative analysis of skin characteristics to identify lesions that require further evaluation by physicians to rule out melanoma. Our June 12, 2007 patent filing relates to ways

we control our MelaFind® system and our September 4, 2007 patent filing surrounds certain dermatology information derived from MelaFind®. Finally our December 14, 2007 filing relates to characterizing the texture of an image.

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 6,000 lesions has been compiled over a number of years and would be difficult to replicate.

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.

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 "pre-amendment" 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' 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. In October of 2004, we 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®. On October 12, 2006, we announced that the FDA had informed us that when submitted, the MelaFind® PMA application would receive expedited review. Expedited review means that upon filing a PMA with the FDA, it is placed at the beginning of the FDA's queue and receives additional review resources. While the expedited review could shorten the MelaFind® FDA approval process, we can give no assurances that this will be the case. Upon obtaining premarket approval from the FDA, we plan to launch MelaFind® in the United States.

However, 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 current Good Manufacturing Practices (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; 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* relaters, 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 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, 2007, we had 30 full-time and 3 part-time employees, of whom 16 were engaged in research and development (including clinical and regulatory affairs), 5 in production (including document control and quality assurance) and 12 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®. On December 11, 2006 we announced that we had signed an exclusive sale and licensing agreement with KaVo, a leading dental equipment manufacturer and subsidiary of Danaher Corporation, to further develop and commercialize DIFOTI®. In accordance with the terms of the agreement, KaVo paid us an up-front sum, and made a second payment to us in July 2007. If KaVo is successful in commercializing DIFOTI®, KaVo will pay us an annual royalty based on the number of systems sold per calendar year following commercial re-launch of DIFOTI® or a set minimum royalty payment, whichever is greater. As a result of this disposition, we do not expect to have any significant continuing responsibility for the DIFOTI® business.

Other

Our Internet address is www.eosciences.com. Our annual report on Form 10-K, quarterly reports on Forms 10-Q, current reports on Forms 8-K, and amendments to those reports are available, without charge, on our website, www.eosciences.com, as soon as reasonably practical after they are filed electronically with the Securities and Exchange Commission (SEC). Copies are also available, without charge, from Electro-Optical Sciences, Inc., 3 West Main Street, Suite 201, Irvington New York, 10533, Attention: Secretary.

Item 1A. ***Risk factors***

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.

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 six 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 payers, 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 the second half of 2008. 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 pre-market approval (PMA) from the Food and Drug Administration (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. On October 12, 2006 we announced that the FDA had informed us that when submitted the MelaFind® PMA application would receive expedited review. Expedited review means that upon filing a PMA application with the FDA, it is placed at the beginning of the FDA's review queue and receives additional review resources. While the expedited review could shorten the MelaFind® FDA approval process, we can give no assurances that this will be the case.

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 payers. The markets for MelaFind® may also be limited by the indications for which its use may be reimbursed.

The availability of medical insurance coverage and reimbursement for newly approved medical devices is uncertain. In the 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 payers.

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

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

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, according to an industry report, Medicare coverage determinations for medical devices lag 15 months to five years or more behind FDA approval for that device. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state by state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the 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, we have a Protocol Agreement with the FDA, and in late January 2007 we commenced 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 have the hardware systems necessary to fully implement our pivotal clinical trial that started in late January 2007. However, the pivotal clinical trial and supporting clinical studies require the involvement of a number of clinical sites 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. To date, there are over 400 melanoma lesions 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 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 have been 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 year ended December 31, 2007 was approximately $11.9 million, and as of December 31, 2007, we had an accumulated deficit of approximately $43.2 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind®. If we receive PMA approval for MelaFind® from the FDA, we expect to incur significant sales and marketing expenses, which will require additional funding, and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

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

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

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

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

The precision optical imaging field is subject to rapid technological change and product innovation. MelaFind® is based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies. Companies in the medical device industry with significantly greater financial, technical, research, marketing, sales and distribution and other resources have expertise and interest in the exploitation of computer-aided diagnosis, medical imaging, and other technologies MelaFind® utilizes. Some of these companies are working on potentially competing products or therapies, including confocal microscopy (a type of scanning microscopy for 3-dimensional specimens, which produces blur-free images at various

depths), various forms of spectroscopy (a study of the way molecules absorb and emit light), other imaging modalities, including molecular imaging in which tagged antibodies search for cancer cell antigens, and molecular and genetic screening tests. Molecular-based approaches are being investigated; Dermtech is exploring Messenger RNA analysis of surface cells, for example. In addition, the National Institutes of Health and other supporters of cancer research are presumptively seeking ways to improve the diagnosis or treatment of melanoma by sponsoring corporate and academic research. There can be no assurance that one or more of these companies will not succeed in developing or marketing technologies and products or services that demonstrate better safety or effectiveness, superior clinical results, greater ease of use or lower cost than MelaFind®, or that such competitors will not succeed in obtaining regulatory approval for introducing or commercializing any such products or services prior to us. FDA approval of a commercially viable alternative to MelaFind® produced by a competitor could significantly reduce market acceptance of MelaFind®. Any of the above competitive developments could have a material adverse effect on our business, financial condition, and results of operations. There is no assurance that products, services, or technologies introduced prior to or subsequent to the commercialization of MelaFind® will not render MelaFind® less marketable or obsolete.

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

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

In addition to the foregoing, our clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous other reasons, including, but not limited to, the following:

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

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

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

In some foreign markets, which we may seek to enter in the future, pricing and profitability of medical devices are subject to government control. In the 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 payers, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of MelaFind® will depend on a number of factors, including:

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

The 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®; however, there can be no assurance that any such recommendations will be obtained. To date, the medical community outside the limited circle of certain dermatologists specializing in melanoma has had little exposure to us and MelaFind®. Because the medical community is often skeptical of new companies and new technologies, we may be unable to gain access to potential customers in order to demonstrate the operation and effectiveness of MelaFind®. Even if we gain access to potential customers, no assurance can be given that members of the dermatological, or later the general practice, medical community will perceive a need for or accept MelaFind®. In particular, given the potentially fatal consequences of failing to detect melanoma at the early, curable stages, practitioners may remain reluctant to rely upon MelaFind® even after we receive approval from the FDA for marketing the product. Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind®. Insufficient market acceptance of MelaFind® would have a material adverse effect on our business, financial condition and results of operations.

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

As of December 31, 2007 we had $20.9 million in cash, cash equivalents and marketable securities. Our operations have consumed substantial amounts of cash for each of the last seven years. We currently believe that our available cash and cash equivalents, including the proceeds from our August 2007 and November 2006 financings and our 2005 initial public offering, will be sufficient to fund our anticipated levels of operations through early 2009. 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 completing the pivotal 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 payers, or the amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind®;
- the cost of commercialization activities, including 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 fully implement this marketing plan. In addition to being expensive, developing such a sales force is time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. Qualified direct sales personnel with experience in the medical device market are in high demand, and there is no assurance that we will be able to hire or retain an effective direct sales team. Similarly, qualified, independent medical device representatives both within and outside the 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 have developed or are developing relationships will have or sustain the ability to produce the quantities of MelaFind® needed for development or commercial sales, or will be willing to do so at prices that allow MelaFind® to compete successfully in the market.

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

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

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

Our manufacturing efforts currently rely on FillFactory, a subsidiary of Cypress Semiconductor Corp., to manufacture and supply the complementary metal oxide semiconductor sensor in MelaFind®, on Carl Zeiss Jena GmbH (Zeiss) for lens and lens objective assemblies, 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 several vendors to perform additional services or produce components for us. There can be no assurance that these third parties will meet their obligations. Each of these suppliers is a sole-source supplier. Our contract manufacturers also rely on sole-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to procure their raw material on time, failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- suppliers may make errors in manufacturing components that could negatively 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 to complete developmental engineering and testing of our hand-held imaging device, and have also entered into a production agreement with ASKION to assemble the components and produce initial quantities of our hand-held imaging devices. We intend to enter into a contract for commercial production of the hand-held imaging devices once commercial specifications for MelaFind® have been finalized, but we may not be able to enter such an agreement on mutually acceptable terms. Failure to enter into such an agreement with ASKION would require us to expand our own manufacturing facilities or obtain such services elsewhere. Similarly, we have entered into a confidentiality agreement and a development agreement with Zeiss for lenses and lens objective assemblies, and we have entered into a contract for the commercial production of lenses. The manufacturing agreement with ASKION will include integration of the Zeiss lenses in the hand-held imaging devices. Our planned reliance upon an outside provider for assembly and production services subjects us to the risk of adverse consequences from delays and defects caused by the failure of such outside supplier to meet its contractual obligations, including confidentiality obligations in the case of Zeiss, which is an affiliate of Carl Zeiss AG, a potential competitor. The failure by us or our supplier to produce a sufficient number of hand-held imaging devices that can operate according to our specifications could delay the 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 the second half of 2008. 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 FDA Quality System Regulation (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. The DIFOTI® inspectional findings were discussed in a subsequent meeting with the FDA on April 28, 2005. An onsite consultant was hired to address these deficiencies and structure a compliant Quality System for MelaFind®. Throughout 2006 we worked to address the deficiencies noted in accordance with the agreement reached with the FDA. On May 18, 2006, the FDA re-audited the Company's facility for a follow-up inspection and audited our revised Quality System. No non-conformities or negative observations were reported to the Company. On December 5, 2006 we received correspondence from the FDA that reported "that all previous observations reported on the FDA-483 were corrected, and this firm no longer manufactures or distributes the DIFOTI® 2.0 dental imaging system."

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

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

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

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

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

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

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

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

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

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

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute which prohibits certain business practices and relationships, including the payment or receipt of

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

The application of the privacy provisions of HIPAA is uncertain.

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

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

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

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

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

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

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

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

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

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if MelaFind® causes, or merely appears to have caused, an injury or if a patient alleges that MelaFind® failed to provide appropriate diagnostic information on a lesion where melanoma was subsequently found to be present. Claims may be made by patients, healthcare providers or others involved with MelaFind®. MelaFind® will require PMA approval prior to commercialization in the US. The clinical studies of MelaFind® are considered by the FDA as “Non-Significant Risk”. Consequently, the trials are conducted under the auspices of an abbreviated Investigational Device Exemption. 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 could adversely impact our business, financial condition and results of operations. While the Company does provide off-site back-up for its critical data which we believe to be sufficient to meet our needs, there can be no assurance that the our current plan can anticipate every possible eventuality.

We may be adversely affected by breaches of online security.

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

We are dependent upon telecommunications and the internet.

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

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

Versions of MelaFind® may rely on radio transmissions from the hand-held imaging device to a base station that may be connected to the internet. Applicable requirements will restrict us to a particular band of frequencies allocated to low power radio service for transmitting data in support of specific diagnostic or

therapeutic functions. Failure to comply with all applicable restrictions on the use of such frequencies, or unforeseeable difficulties with the use of such frequencies, could impede our ability to commercialize MelaFind®.

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

All of our operations are conducted at two adjacent buildings in Irvington, New York. We take precautions to safeguard our facility, including insurance, health and safety protocols, contracted off-site engineering services, 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., MBA, our President and Chief Executive Officer and Dina Gutkowicz-Krusin, Ph.D., our Director of Clinical Research. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel.

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

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

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

We have granted to certain employees stock options that vest with the attainment of various performance milestones. Upon the attainment of these milestones we will be required to recognize a stock based compensation expense in an amount based on the fair value of the options. We have also granted options that vest upon attainment of development milestones. Upon the attainment of each of the relevant development milestones there could be a significant compensation charge based on the then fair value of such options.

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

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

Risks Relating to our Common Stock

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

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

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

Our stock price has been and is likely to continue to be volatile. Between October 28, 2005 (the date of our initial public offering) and December 31, 2007, our stock price has ranged from $4.05 to $8.92 per share. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:

- results of our research and development efforts and our clinical trials;
- the timing of regulatory approval for our products;
- failure of any of our products, if approved, to achieve commercial success;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the US and foreign countries;
- ability to manufacture our products to commercial standards;
- developments concerning our clinical collaborators, suppliers or marketing partners;
- changes in financial estimates or recommendations by securities analysts;
- public concern over our products;
- developments or disputes concerning patents or other intellectual property rights;
- product liability claims and litigation against us or our competitors;
- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of and third-party reimbursement in the 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 29, 2008, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates in the aggregate, beneficially owned approximately 48.3% of our outstanding common stock. As a result, these stockholders, subject to any fiduciary duties owed to our other stockholders under Delaware law, could be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your interests. The concentration of ownership could delay or prevent a change in control of our company or otherwise discourage a potential acquirer from attempting to obtain control of our company, which in turn could reduce the price of our common stock. In addition, these stockholders, some of whom have representatives sitting on our Board of Directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes of control of our company, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

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

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

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

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

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

Item 1B. ***Unresolved Staff Comments.***

Not applicable.

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 7,450 square feet of office, laboratory, and assembly space in an adjacent building with the street address of 1 Bridge Street, Suites 11 and 15, Irvington, New York. The lease on the

2,800 square feet of space expires in January 2011. On the 1 Bridge Street property, the lease on 4,950 square feet of space expires in June 2009 and the lease on 2,500 square feet acquired in August 2007 expires in January 2011. We believe that these facilities are adequate to meet our current and reasonably foreseeable requirements. We believe that we will be able to obtain additional space, if required, on commercially reasonable terms.

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 2007.

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 of January 1, 2006 through December 31, 2007 as reported by the NASDAQ Capital Market:

	High	Low
Year Ended December 31, 2007		
October 1 — December 31, 2007	$ 5.96	$ 4.05
July 1 — September 30, 2007	$ 6.79	$ 5.25
April 1 — June 30, 2007	$ 7.46	$ 4.29
January 1, 2007 — March 31, 2007	$ 7.10	$ 4.50
Year Ended — December 31, 2006		
October 1 — December 31, 2006	$ 8.10	$ 5.26
July 1 — September 30, 2006	$ 7.34	$ 4.74
April 1 — June 30, 2006	$ 8.92	$ 5.52
January 1, 2006 — March 31, 2006	$ 6.20	$ 5.20

As of February 29, 2008, there were approximately 191 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 8- Stock-Based Compensation and Warrants to the financial statements contained in Part II Item 8 of this annual report.

Use of Proceeds from the Sale of 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 expenses in conjunction with the initial public offering were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any 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.

Use of Proceeds from the Sale of Unregistered Securities

On October 31, 2006 the Company entered into securities purchase agreements and a registration rights agreement with certain accredited investors for the private placement of 2,312,384 shares of the Company's common stock and warrants to purchase up to 346,857 shares of the Company's common stock for aggregate gross proceeds of approximately $13.2 million, and approximately $12.5 million in net proceeds. The transaction closed November 3, 2006. Pursuant to the securities purchase agreements, for a purchase price of $5.70 each investor received one share of the Company's common stock and a warrant to purchase 0.15 of a share of common stock. The warrants are five-year warrants with an exercise price of $6.70 per share

On July 31, 2007, the Company entered into a securities purchase agreement and a registration rights agreement with certain accredited investors for the private placement of 2,000,178 shares of the Company's common stock and warrants to purchase up to 500,041 shares of the Company's common stock for aggregate gross proceeds of approximately $11.5 million and net proceeds of approximately $10.7 million. The private placement closed August 3, 2007. Pursuant to the securities purchase agreement, for a purchase price of $5.75 each investor received one share of the Company's common stock and a warrant to purchase 0.25 of a share of common stock. The warrants are five-year warrants with an exercise price of $8.00 per share.

Both of the private placements were completed pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder.

Pursuant to the terms of the registration rights agreements, the Company filed resale registration statements covering the shares in both private placements, including the shares issuable upon exercise of the warrants, with the SEC. In the unlikely event that the Company fails to meet certain obligations, as described in the registration rights agreements, the holders would be entitled to certain monetary damages.

However, in no event is the Company obligated to make payments in excess of 10% of the aggregate purchase price of the common shares. The Company has concluded that it is unlikely that the Company would be required

to remit any payments to its investors for failing to maintain its effectiveness. The Company's resale registration statements on Form S-3 were declared effective by the Securities and Exchange Commission (Registration No. 333-139056 and Registration No. 333-145740) on February 12, 2007 and September 11, 2007, respectively.

No payments for expenses in conjunction with the 2006 private placement were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any 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 cash with a commercial bank, 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.

Item 6. ***Selected Financial Data***

The following table sets forth selected financial data. The financial information for the years ended December 31, 2005, 2006, and 2007 and as of December 31, 2006 and 2007 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, 2003 and 2004 and as of December 31, 2003, 2004, and 2005 have 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.

	Year Ended December 31,				
	2003	2004	2005	2006	2007
	(In thousands, except share and per share data)				
Statements of Operations Data:					
Research and development expenses	$ 828	$ 1,892	$ 3,822	$ 7,574	$ 7,678
General and administrative expenses	1,034	1,234	2,636	4,526	5,400
Operating loss from continuing operations	(1,862)	(3,126)	(6,458)	(12,100)	(13,078)
Interest expense/(income)	76	67	(174)	(728)	(1,054)
Other income	—	—	—	—	(59)
Loss from continuing operations	(1,938)	(3,193)	(6,284)	(11,372)	(11,965)
(Loss) gain from discontinued operations	(12)	(426)	(442)	781	28
Net loss	(1,950)	(3,619)	(6,726)	(10,591)	(11,937)
Preferred stock deemed dividends	(322)	(676)	(1,199)	—	—
Preferred stock accretion	(25)	(258)	(1,077)	—	—
Stock distribution of preferred Series B shares	(102)	—	—	—	—
Net loss attributable to common stockholders	$ (2,399)	$ (4,553)	$ (9,002)	$ (10,591)	$ (11,937)
Net loss per share, basic and diluted:					
Continuing operations	$ (1.48)	$ (2.34)	$ (2.44)	$ (1.01)	$ (0.84)
Discontinued operations	(0.01)	(0.24)	(0.13)	.07	—
Basic and diluted net loss per common share	$ (1.49)	$ (2.58)	$ (2.57)	$ (.94)	$ (0.84)
Basic and diluted weighted average number of common shares outstanding	1,614,897	1,766,608	3,508,835	11,293,783	14,220,466

	As of December 31,				
	2003	2004	2005	2006	2007
	(In thousands, except share and per share data)				
Balance Sheet Data:					
Total current assets	$ 217	$ 6,813	$ 18,873	$ 21,771	$ 21,328
Total assets	432	7,096	19,166	22,476	22,108
Total liabilities	650	691	916	1,162	1,336
Redeemable convertible preferred stock	4,067	9,955	—	—	—
Accumulated deficit	(10,288)	(13,907)	(20,633)	(31,225)	(43,162)
Total stockholders' (deficiency)/equity	(4,285)	(3,550)	18,249	21,314	20,772

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, 2007 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®. On December 11, 2006 we announced that we had signed an exclusive licensing agreement with KaVo, a leading dental equipment manufacturer, to further develop and commercialize DIFOTI®. In accordance with the terms of the agreement, KaVo paid us an up-front sum and made a second payment to us in July 2007. If KaVo is successful in commercializing DIFOTI®, KaVo will pay us an annual royalty based on the number of systems sold per calendar year following their commercial re-launch of DIFOTI® or a set minimum. With the completion of this transaction we do not expect to have any significant continuing responsibility for the DIFOTI® business.

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 that began in late January 2007 and its patient enrollment. We believe that period-to-period comparisons of our results of operations may not be 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, 2007, we had an accumulated deficit of $43.2 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, we completed an initial public offering. We 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. On October 31, 2006

we entered into securities purchase agreements and a registration rights agreement with certain accredited investors for the private placement of 2,312,384 shares of the Company's common stock and warrants to purchase up to 346,857 shares of the Company's common stock for aggregate gross proceeds of approximately $13.2 million and net proceeds of approximately $12.5 million. The transaction closed November 3, 2006. On July 31, 2007, the Company entered into a securities purchase agreement and registration rights agreement with certain accredited investors for the private placement of 2,000,178 shares of the Company's common stock and warrants to purchase up to 500,041 shares of the Company's common stock for aggregate gross proceeds of approximately $11.5 million and net proceeds of approximately $10.7 million. This transaction closed on August 3, 2007.

We believe that the proceeds from these three transactions will be sufficient to fund our anticipated level of operations through early 2009. We will however 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, 2007 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 and general corporate activities and costs associated with our efforts 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 the planned expansion of our business. 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, 2007, we had available net operating loss carryforwards for federal income tax reporting purposes of approximately $16.6 million. The net operating loss carryforwards may be available to offset future taxable income expiring at various dates through the year 2027. 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

The Company has not received FDA approval for the sale of MelaFind® and has had no revenues from products since the 2005 discontinuance of DIFOTI® operations.

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."

Prior to January 1, 2006 we applied the intrinsic-value method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations to account for our fixed-plan employee stock options. Under this method, no compensation expense had been recorded for awards granted with no intrinsic value. Namely, on the date of grant only if the then current market price of the underlying stock exceeded the exercise price would there be a compensation charge. 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" established accounting and disclosure requirements using a fair-value based method of accounting for stock-based employee compensation plans. As allowed by SFAS Nos. 123 and 148, we elected to continue to apply the intrinsic-value based method of accounting for employee stock options described above until January 1, 2006 and adopted only the disclosure requirements of SFAS 123. 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 closing price of our common stock on the measurement date.

Effective January 1, 2006, we began recording compensation expense associated with stock options and other forms of equity compensation in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), as interpreted by SEC Staff Accounting Bulletins No. 107 and No. 110. The Company adopted the modified prospective transition method provided for under SFAS 123R, and consequently, has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options recognized in 2006 includes: 1) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006 over the requisite service period based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*; and 2) amortization related to all stock option awards granted on or subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. A compensation charge is recorded when it is probable that performance conditions will be satisfied. The probability of vesting is updated at each reporting period and compensation is adjusted via a cumulative catch-up adjustment or prospectively depending upon the nature of the change.

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.

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 and accrue for such costs 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, 2007 Compared to Year Ended December 31, 2006

Research and Development Expense

Research and development expense increased by $103 to $7,678 for the year ended December 31, 2007 from $7,575 for the year ended December 31, 2006. As we have noted throughout 2007, our total research and development spending trend remained consistent with 2006. However, there was a shift in the components of this spending. Our clinical trial costs increased by $653 and the technical support necessary to support the clinical trails increased by $208. In addition, spending on our quality systems increased $126 as we continue to works towards developing and documenting processes and procedures for FDA review. Offsetting these increases, production costs decreased $328, regulatory spending decreased $150, software development and other research decreased $137 and share based compensation costs decreased $269.

General and Administrative Expense

General and administrative expense increased by $874 to $5,400 for the year ended December 31, 2007 from $4,526 for the year ending December 31, 2006. The increase was attributable to an increase in marketing costs of $714, the majority of which was incurred in connection with market research designed to allow us to properly position the Melafind® system following FDA approval. As we grow and mature our costs have increased in several areas including; travel expenses $174, recruiting costs $142, legal costs for patent work $140, depreciation $76, rent and utilities $69, and salaries $41. These increases were offset by declines in several spending areas including corporate legal work which decreased $218, and temporary help costs which were $94 lower. In addition, share based compensation costs decreased $191.

Interest (Income)/Expense

Interest income for the year ended December 31, 2007 was $1,054 compared to $728 for the year ended December 31, 2006. The increase for the year ended December 31, 2007 was directly attributable to an increase in cash and cash equivalents generated as a result of our financings in November 2006 and August 2007 along with the 2007 proceeds from the sale and licensing of our DIFOTI® assets.

Other Income

Other income for the year ended December 31, 2007 totaling $59 consisted of amounts earned under our contract with L'Oreal.

Gain (Loss) from Discontinued Operations

There was a gain of $28 on the sale of discontinued operations in the year ended December 31, 2007. Costs associated with the transaction with KaVo were lower than expected and the December 31, 2006 accrual to capture these expenses was partially reversed in 2007.

Year Ended December 31, 2006 Compared to Year Ended December 31, 2005

Research and Development Expense

Research and development expense increased by $3,753 to $7,575 for the year ended December 31, 2006 from $3,822 for the year ended December 31, 2005. This increase was primarily attributable to a step-up of $2,483 in product development costs associated with MelaFind®. Approximately $1,700 of the increase was spent with ASKION, and approximately $540 of the increase was spent with several other suppliers to our R&D program. In addition we had an increase in personnel costs of $437, an increase in our clinical study costs of $121 and an increase in costs associated with our regulatory and FDA work of $87. We currently expect at least this level of spending to continue for 2007.

In addition we recorded a $623 share-based compensation charge for certain research and development personnel for the year ended December 31, 2006. This expense includes charges in accordance with SFAS 123R, related to the issuance of stock options.

General and Administrative Expense

General and administrative expense increased by $1,890 to $4,526 for the year ended December 31, 2006 from $2,636 for the year ended December 31, 2005. The increase was attributable to higher personnel costs of $184 and reimbursement and pre-marketing activities of $283. Higher costs associated with our status as a public company for an entire year totaled $829 and consisted primarily of increased legal fees of $420, accounting and related services of $259, and stockholder relations costs of $150. We also incurred higher insurance costs of $180 that were primarily related to increased directors and officers insurance coverage. Additionally, our franchise tax expense increased by $98, and we incurred increased strategic consulting expenses of $235. Our general overhead also increased by $306, which included a rent increase of $53.

In addition we recorded a $412 share based compensation charge in accordance with SFAS 123R. During 2005 we recorded a share based compensation charge of $638 that was principally related to the immediate vesting of 125,000 options upon completion of our initial public offering. Therefore, for 2006 we had a decrease in share based compensation of $226.

Interest (Income)/Expense

Interest income for the year ended December 31, 2006 was $728 compared to $174 for the year ended December 31, 2005. The increase for the year ended December 31, 2006 was directly attributable to an increase in cash and cash equivalents generated as a result of our initial public offering on October 28, 2005 and our November 2006 financing along with the proceeds from the sale and licensing of our DIFOTI® assets.

Gain (Loss) from Discontinued Operations

The gain on the sale and licensing of our discontinued operations in the year ended December 31, 2006 was $781, compared with the loss on discontinued operations of $442 for the year ended December 31, 2005. The gain in 2006 resulted from the sale and licensing transaction of DIFOTI® assets with KaVo, and the 2005 loss related to our decision to discontinue DIFOTI® operations in April 2005.

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, 2007, we had $20,916 in cash, cash equivalents and marketable securities as compared to $20,940 of cash and cash equivalents at December 31, 2006, for a decrease of $24. The decrease resulted primarily from the net proceeds of approximately $10,716 from the Company's August 2007 private placement, and proceeds from the sale and licensing of the DIFOTI® assets of approximately $500. This was offset by cash used in operating activities and the purchase of marketable securities. Our cash and cash equivalents at December 31, 2007 are liquid investments in cash with a commercial bank, investment grade securities, and money market accounts.

Cash Flows from Operating Activities

Net cash used in operations was $11,049 for the year ended December 31, 2007. For the years ended December 31, 2005 and 2006 the net cash used in operations was $5,831 and $10,141 respectively. For all periods, cash used in operations was attributable primarily to net losses after adjustment for non-cash charges related to non-cash compensation, depreciation and other changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in our investing activities was $1,524 for the year ended December 31, 2007 principally relating to the purchase of marketable securities, fixed assets and patent costs offset by the proceeds received from the sale and licensing of our DIFOTI® assets. For the year ended December 31, 2006, net cash used in our investing activities was $44 principally relating to the purchase of fixed assets and patent costs offset by the proceeds received from the sale and licensing of our DIFOTI® assets. For the year ended December 31, 2005, net cash provided by investing activities was $6,502, which was principally related to the redemption of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $10,830 for the year ended December 31, 2007 and reflects the net proceeds received from our August 3, 2007 private placement financing. For the years ended December 31, 2005 and 2006 the net cash flows provided by financing activities were $17,725 and $12,620 respectively. In 2005, financing cash flows reflect proceeds from the initial public offering. In 2006, financing cash flows reflects the net proceeds from the November 2, 2006 private placement.

Operating Capital and Capital Expenditure Requirements

We face certain risks and uncertainties, which are present in many emerging medical device companies. At December 31, 2007, we had an accumulated deficit of $43.2 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 initial public offering and our November 3, 2006, and our August 2, 2007 financings, 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 early 2009. If our existing cash is 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 would 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 payers, or the amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind®;
- the cost of commercialization activities, including 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, 2007 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	3-5 Years	More Than 5 Years
			(Dollars in thousands)		
Operating Leases	$ 777	$ 320	$ 442	$ 15	—
Total	$ 777	$ 320	$ 442	$ 15	—

Our long-term obligations are two non-cancelable operating leases for space. The lease on 2,800 square feet of office space expires in January 2011. The lease on our laboratory, assembly, and office space, originally 4,950 square feet (expiring in June 2009) was amended in August 2007 to include an additional 2,500 square feet of office space (expiring in January 2011).

Related Party Transactions (see Note 9)

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

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141R, Business Combinations. This Statement replaces FASB SFAS No. 141. SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We are currently assessing the impact the adoption of SFAS 141R will have on our financial position and results of operations.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51. This Statement amends ARB 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. In addition to the amendments to ARB 51, this Statement amends FASB Statement No. 128, Earnings per Share; so that earnings-per-share data will continue to be calculated the same way those data were calculated before this Statement was issued. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect the adoption of this pronouncement to have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment to SFAS No. 115” (SFAS 159). This statement permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reporting earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This statement is expected to expand the use of fair value measurements, which is consistent with FASB’s long-term measurement objectives for accounting for financial instruments. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We do not expect that the adoption of SFAS 159 will have a material impact on our financial statements.

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements” (SFAS 157). This statement defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007; however, earlier application is encouraged. We do not expect the adoption of SFAS 157 to have a material impact on our financial statements.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

Our exposure to market risk at December 31, 2007 is confined to our cash and cash equivalents. We invest in cash and certificates of deposit with a commercial bank, investment grade securities, and money market accounts. We currently do not hedge interest rate exposure. While declines in interest rates do impact the amount of interest income that our cash, cash equivalents and marketable securities will earn, we do not believe that we have any material exposure to interest rate risk arising from our investments, due to the short-term nature of our investments.

Item 8. ***Financial Statements and Supplementary Data***

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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, 2006 and 2007, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2007. 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, 2006 and 2007, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the financial statements, effective January 1, 2006 the Company changed its method of accounting for stock-based compensation in accordance with Statement of Financial Accounting Standards No. 123 (Revised 2004) "Share-Based Payment".

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Electro-Optical Sciences, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 10, 2008 expressed an unqualified opinion thereon.

/s/ Eisner, LLP

New York, New York
March 10, 2008

ELECTRO-OPTICAL SCIENCES, INC.

BALANCE SHEETS

	December 31, 2006	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents (includes $12,000,000 in certificates of deposit as of December 31, 2006)	$ 20,939,527	$ 19,196,589
Marketable securities	—	1,719,905
Receivable from sale and licensing of discontinued operations, net	487,680	—
Prepaid expenses and other current assets	343,634	411,554
Total Current Assets	21,770,841	21,328,048
Property and equipment, net	564,471	616,110
Patents and trademarks, net	100,630	118,138
Other assets	39,758	45,876
Total Assets	$ 22,475,700	$ 22,108,172
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable (includes related parties of $53,987 as of December 31, 2006)	$ 641,036	$ 567,987
Accrued expenses (includes related parties of $34,257 and $10,000 as of December 31, 2006 and 2007, respectively)	504,670	674,711
Deferred income	—	74,946
Other current liabilities	16,077	18,804
Total Current Liabilities	1,161,783	1,336,448
COMMITMENTS AND CONTINGENCIES (Note 5)		
Stockholders' Equity:		
Preferred stock — $0.10 par value; authorized 10,000,000 shares:		
Issued and outstanding: none	—	—
Common stock — $0.001 par value; authorized 30,000,000 shares:		
Issued and outstanding 13,296,448 and 15,401,882 shares at December 31, 2006 and 2007, respectively.	13,296	15,402
Additional paid-in capital	52,525,408	63,930,689
Other comprehensive loss	—	(12,136)
Accumulated deficit	(31,224,787)	(43,162,231)
Total Stockholders' Equity	21,313,917	20,771,724
Total Liabilities and Stockholders' Equity	$ 22,475,700	$ 22,108,172

The accompanying notes are an integral part of these financial statements

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF OPERATIONS

	Year Ended		
	December 31, 2005	December 31, 2006	December 31, 2007
Operating expenses:			
Research and development	$ 3,821,712	$ 7,574,744	$ 7,677,578
General and administrative	2,636,064	4,525,789	5,400,371
Operating loss from continuing operations	(6,457,776)	(12,100,533)	(13,077,949)
Interest income	(173,888)	(728,053)	(1,054,130)
Other income	—	—	(58,567)
	(173,888)	(728,053)	(1,112,697)
Loss from continuing operations	(6,283,888)	(11,372,480)	(11,965,252)
Loss from discontinued operations	(442,459)	—	—
Gain on sale and licensing of discontinued operations	—	781,003	27,808
Net loss	(6,726,347)	(10,591,477)	(11,937,444)
Less:			
Preferred stock deemed dividends	1,198,439	—	—
Preferred stock accretion	1,077,492	—	—
Net Loss Attributable to Common Stockholders	$ (9,002,278)	$ (10,591,477)	$ (11,937,444)
Net income (loss) per common share, basic and diluted:			
Continuing operations	$ (2.44)	$ (1.01)	$ (0.84)
Discontinued operations	(0.13)	.07	—
Basic and diluted net loss per common share	$ (2.57)	$ (0.94)	$ (0.84)
Basic and diluted weighted average number of common shares outstanding	3,508,835	11,293,783	14,220,466

The accompanying notes are an integral part of these financial statements

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2005, 2006 and 2007

	Convertible Preferred Stock Series A		Common Stock		Additional Paid-in Capital	Notes Receivable	Deferred Compensation	Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount						
Balance at January 1, 2005	198,000	$ 972,311	1,809,758	$ 1,810	$ 9,611,094	$ (69,000)	$ (159,300)		$ (13,906,963)	$ (3,550,048)
Preferred stock accretion					(1,077,492)					(1,077,492)
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)					
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
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
Exercise of options			135,450	136	87,929					88,065
Exercise of warrants			10,781	10	26,418					26,428
Amortization of deferred compensation							62,610			62,610
Issuance of shares of common stock and warrants in connection with private placement (net of expenses)			2,312,384	2,312	12,503,075					12,505,387
Issuance of options to consultant					161,934					161,934
Share-based compensation expense					811,632					811,632
Net loss									(10,591,477)	(10,591,477)
Balance at December 31, 2006			13,296,448	$ 13,296	$ 52,525,408				$ (31,224,787)	$ 21,313,917
Exercise of Options			105,256	106	114,421					114,527
Issuance of shares of common stock and warrants in connection with private placement (net of expenses)			2,000,178	2,000	10,713,847					10,715,847
Issuance of options to consultant					139,703					139,703
Share-based compensation expense					437,310					437,310
Other Comprehensive loss								(12,136)		(12,136)
Net loss									(11,937,444)	(11,937,444)
Comprehensive loss (sub-total)										(11,949,580)
Balance at December 31, 2007			15,401,882	$ 15,402	$ 63,930,689			(12,136)	$ (43,162,231)	$ 20,771,724

The accompanying notes are an integral part of these financial statements

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF CASH FLOWS

	Year Ended		
	December 31, 2005	December 31, 2006	December 31, 2007
Cash flows from operating activities:			
Loss from continuing operations	$ (6,283,888)	$ (11,372,480)	$ (11,965,252)
Loss from discontinued operations	(442,459)	—	—
Gain on sale and licensing of discontinued operations	—	781,003	27,808
Net loss	(6,726,347)	(10,591,477)	(11,937,444)
Adjustments to reconcile net loss to net cash used in operating activities:			
Allowance for doubtful accounts	(1,000)	—	—
Gain on sale of discontinued operations	—	(781,003)	(27,808)
Depreciation and amortization	49,098	138,358	223,706
Noncash compensation and amortization of deferred compensation	672,800	874,241	437,310
Amortization of unearned interest income-discontinued operations	—	—	(12,320)
Common stock options and warrants issued for consulting fees	138,000	161,934	139,703
Retirement of stock subscription receivable for consulting services	34,500	—	—
Amortization of discount on marketable securities	(33,502)	—	(519)
Changes in operating assets and liabilities:			
Decrease in receivables	8,128	—	—
Increase in inventories	(16,122)	—	—
Increase in prepaid expenses and other current assets	(181,507)	(132,694)	(67,920)
Increase in accounts payable and accrued expenses	332,110	196,193	124,800
Decrease in deferred revenues	(106,335)	—	—
(Decrease) increase in other current liabilities	(456)	(751)	2,727
Increase in other assets	—	(6,146)	(6,118)
Increase in deferred income	—	—	74,946
Net cash used in operating activities	(5,830,633)	(10,141,345)	(11,048,937)
Cash flows from investing activities:			
Patent costs	(5,316)	(35,491)	(40,006)
Purchases of property and equipment	(121,239)	(508,547)	(252,847)
Sale (purchase) of marketable securities	6,628,253	—	(1,731,522)
Proceeds from sale and licensing of discontinued operations	—	500,000	500,000
Net cash provided by (used in) investing activities	6,501,698	(44,038)	(1,524,375)
Cash flows from financing activities:			
Proceeds from private placement financing	—	13,180,598	11,501,023
Expenses related to private placement financing	—	(675,211)	(785,176)
Proceeds from exercise of stock options	—	88,065	114,527
Proceeds from exercise of stock warrants	—	26,428	—
Proceeds from Initial Public Offering	21,311,500	—	—
Expenses related to Initial Public Offering	(3,624,972)	—	—
Proceeds from sale of common stock	38,732	—	—
Net cash provided by financing activities	17,725,260	12,619,880	10,830,374
Net increase (decrease) in cash and cash equivalents	18,396,325	2,434,497	(1,742,938)
Cash and cash equivalents at beginning of year	108,705	18,505,030	20,939,527
Cash and cash equivalents at end of year	$ 18,505,030	$ 20,939,527	$ 19,196,589
Supplemental Schedule of Noncash Investing and Financing Activities:			
Receivable from sale and licensing of discontinued operations	—	$ 487,680	—
Preferred stock accretion	$ 1,077,492	—	—
Reclassification of inventories and patents to assets held for sale	$ 156,677	—	—
Unrealized loss on marketable securities	—	—	$ 12,136

The accompanying notes are an integral part of these financial statements

ELECTRO-OPTICAL SCIENCES, INC.

Notes to Financial Statements
(In thousands, except for share and per share data)
(For the Years Ended December 31, 2007, 2006 and 2005)

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

Organization and Business

Electro-Optical Sciences, Inc. (EOS), 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 clinical trial and establishment of the safety and effectiveness of the MelaFind® device. On October 12, 2006, the Company announced that the FDA informed the Company that when submitted, the MelaFind® premarket approval, or PMA, application would receive expedited review. Expedited review means that upon filing a PMA with the FDA, it is placed at the beginning of the FDA's queue and receives additional review resources. While the expedited review could shorten the MelaFind® FDA approval process, there can be no assurance that this will be the case. Upon obtaining premarket approval from the FDA, the Company plans to launch MelaFind® in the United States. The pivotal clinical trial commenced in January 2007. If the pivotal trial and FDA approval process proceeds as anticipated, management believes that PMA approval could come as early as the second half of 2008.

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 the 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®. As more fully described in Note 10, in December 2006, the Company sold and licensed its rights to the DIFOTI® assets and does not expect to have any significant continuing responsibility for the DIFOTI® business or products.

At December 31, 2007, the Company has an accumulated deficit of $43.2 million 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 subsequently sold common stock as part of an initial public offering on October 28, 2005 and private placements in November 2006 and August 2007 (refer to Note 7, "Stockholders' Equity," for further details). The Company believes that the proceeds from these transactions will permit the Company to fund anticipated levels of operations through early 2009. However, the Company will require additional funds to achieve significant commercialization of MelaFind®. 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®.

Cash and Cash Equivalents

The Company maintains cash in certificates of deposit and bank deposit accounts which, at times, may exceed federally insured limits. The Company has not experienced any losses on these accounts. Cash

equivalents are 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 are classified in accordance with SFAS No. 115, *"Accounting for Certain Investments in Debt and Equity Securities."* Held-to-maturity marketable securities are reported at amortized cost. Available for sale marketable securities are reported at fair value, with unrealized gains and losses excluded from earnings, and reported in other comprehensive income. Trading securities are reported at fair value, with unrealized gains and losses included in earnings. The Company evaluates declines in fair value of its investments in available-for-sale marketable securities to determine if these declines are other than temporary. When a decline in value is determined to be other-than-temporary, an impairment charge would be recorded and a new cost basis in the investment would be established.

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

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

Income Taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, "Accounting for Income Taxes," which requires the use of the asset and liability method of accounting for deferred income taxes (see Note 11).

The provision for income taxes includes federal, state and local income taxes currently payable and deferred taxes resulting from temporary differences between the financial statement and tax bases of assets and liabilities. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized.

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the US 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. The most significant estimates relate to stock-based compensation arrangements and accrued expenses. 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

Prior to January 1, 2006, the Company applied 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, no compensation expense has been recorded for awards granted with no intrinsic value. Namely, on the date of grant only if the then current market price of the underlying stock exceeded the exercise price would there be a compensation charge. 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 elected to continue to apply the intrinsic-value based method of accounting for employee stock options described above until January 1, 2006, and had 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 for the year ended December 31, 2005 would have been adjusted to the pro forma amounts indicated below:

Net loss attributable to common stockholders, as reported	$ (9,002)
Add: stock-based employee compensation included in reported net loss, net of income tax effect	638
Deduct: stock-based employee compensation expense determined under fair-value-based method, net of related tax effect	(539)
Pro forma net loss	$ (8,903)
Basic and diluted loss per share, as reported	$ (2.57)
Basic and diluted loss per share, pro forma	$ (2.54)

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

Expected volatility	60%
Risk free interest rate	4.39%
Stock option life (in years)	5
Expected dividend yield	0%

Effective January 1, 2006, the Company began recording compensation expense associated with stock options and other forms of equity compensation in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), as interpreted by SEC Staff Accounting Bulletins No. 107 and No. 110. The Company adopted the modified prospective transition method provided

for under SFAS 123R, and consequently, has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options recognized in 2006 includes: (1) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006 over the requisite service period based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*; and (2) amortization related to all stock option awards granted on or subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. A compensation charge is recorded when it is probable that performance conditions will be satisfied. The probability of vesting is updated at each reporting period and compensation is adjusted via a cumulative catch-up adjustment or prospectively depending upon the nature of the change.

As a result of the adoption of SFAS 123R, incremental compensation expense for the year ended December 31, 2006 amounted to $812. At December 31, 2007, total unrecognized compensation cost amounted to approximately $2,858 with respect to 1,054,966 unvested options of which $2,657 of unrecognized compensation cost and 987,188 unvested options relate to development milestones, which will be amortized over the requisite service period or period to the attainment of certain milestones.

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 is reached, as defined in EITF 96-18. Under this method of accounting, the Company estimates the total amount of deferred compensation when the grant is issued for the entire option value based on the Black-Scholes valuation model. Subsequently, the deferred compensation is adjusted each reporting period until vesting occurs and the charge is taken. Compensation attributable to non-vested options is not recorded until vesting occurs (see Note 8).

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 and warrants which are summarized as follows:

	Year Ended December 31,		
	2005	2006	2007
Common stock options	1,115,415	1,689,412	1,812,084
Warrants	298,280	626,845	1,126,886
Total	1,413,695	2,316,257	2,938,970

ELECTRO-OPTICAL SCIENCES, INC.

Notes to Financial Statements — (Continued)

Comprehensive loss

Comprehensive loss includes net loss and unrealized gains and losses on available-for-sale marketable securities. Cumulative unrealized gains and losses on available-for-sale marketable securities, if any, are reflected as accumulated other comprehensive loss in stockholders' equity on the Company's balance sheet. For each of the years ended December 31, 2005 and 2006, net loss was equal to comprehensive loss as there were no unrealized gains or losses on available-for-sale marketable securities at the respective year ends. For the year ended December 31, 2007, comprehensive loss was $11,949 which includes a net loss of $11,937 and an unrealized loss on available-for-sale marketable securities of $12.

Recent Accounting Developments

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141R, Business Combinations. This Statement replaces FASB SFAS No. 141. SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We are currently assessing the impact the adoption of SFAS 141R will have on our financial position and results of operations.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51. This Statement amends ARB 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. In addition to the amendments to ARB 51, this Statement amends FASB Statement No. 128, Earnings per Share so that earnings-per-share data will continue to be calculated the same way those data were calculated before this Statement was issued. This Statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not except the adoption of this pronouncement to have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment to SFAS No. 115" ("SFAS No. 159"). This statement permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reporting earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This statement is expected to expand the use of fair value measurements, which is consistent with FASB's long-term measurement objectives for accounting for financial instruments. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company does not expect that the adoption of SFAS No. 159 will have a material impact on the Company's financial statements.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements." This statement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007; however, earlier application is encouraged. The Company does not expect the adoption of SFAS 157 will have a material impact on its financial statements.

ELECTRO-OPTICAL SCIENCES, INC.

Notes to Financial Statements — (Continued)

2. Marketable Securities:

All marketable securities purchased during 2006 consisted of available-for-sale securities which were held to redemption prior to December 31, 2006 and experienced no gain or loss. On December 31, 2007 marketable equity securities consisted of available-for-sale securities. The Company has experienced a temporary unrealized loss of $12 on several of these securities.

3. Property and Equipment:

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

	December 31,		
	2006	2007	Estimated Useful Life
Leasehold improvements	$ 154	$ 184	Lease Term
Laboratory and research equipment	497	672	5 years
Office furniture and equipment	265	313	5 years
	916	1,169	
Accumulated depreciation and amortization	352	553	
	$ 564	$ 616	

Depreciation expense amounted to approximately $34, $120 and $201 for the years ended December 31, 2005, 2006 and 2007, respectively.

4. Patents:

Patents as shown in the accompanying balance sheets are net of accumulated amortization of $134 and $156 at December 31, 2006 and 2007, respectively. In connection with the discontinuance of DIFOTI® operations in April 2005, patents with a net book value of $71 had been reclassified as assets held for sale, and were subsequently written off in connection with the December 2006 sale and licensing agreement with KaVo. Amortization expense related to all non-DIFOTI® patents was approximately $15, $18 and $22 for the years ended December 31, 2005, 2006 and 2007, respectively. Amortization expense of currently held non-DIFOTI® patents is expected to amount to $23, $23, $23, $23, and $21 for the years ended December 31, 2008, 2009, 2010, 2011, and 2012, respectively.

5. Commitments and Contingencies:

The Company is obligated under two non cancelable operating leases for office space expiring June 2009 and January 2011. The leases are subject to escalations for increases in operating expenses. The approximate aggregate minimum future payments due under these leases are as follows:

Year ended December 31,	
2008	$ 320
2009	256
2010	186
2011	15
	$ 777

Rent expense charged to operations amounted to approximately $202, $255 and $305 for the years ended December 31, 2005, 2006, and 2007, respectively.

In August 2006, the Company engaged Zeiss to build the lenses and assemblies, as well as provide certain technical consulting, for the MelaFind® units which will be used in the Company's pivotal clinical trials. This work was done throughout 2007 and is expected to continue throughout 2008. Total payments to Zeiss amounted to $120 in 2006 and $111 in 2007.

In January 2006, the Company entered into an agreement with ASKION to produce and test commercial grade MelaFind® hand-held imaging device systems. Under the agreement, ASKION is to produce imaging devices for the Company to be utilized in the Company's pivotal trial and at data collection sites in the United States and Europe. The Company is required to make payments to ASKION upon delivery of the MelaFind® systems. We expect to maintain a relationship, which has evolved as a month-to-month agreement, with ASKION. This relationship continued for all or 2007 and we expect to continue with development activities throughout 2008. Total payments to ASKION amounted to $2,473 in 2006 and $2,333 in 2007.

During January 2004, the Company entered into an employment agreement with its President and Chief Executive Officer (Dr. Joseph Gulfo) through December 31, 2005, which provided for a base salary of $175, stock options, and performance bonuses. The agreement provides for automatic one year renewal terms and renewed automatically for the years 2006 and 2007. The Board of Directors increased his salary to $235 and awarded a bonus in the amount of $50 effective May 31, 2006, and effective April 1, 2007, increased his salary to $260 and awarded a bonus in the amount of $60.

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.

6. 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. Company contributions to this plan amounted to approximately $35, $42 and $38 for the years ended December 31, 2005, 2006 and 2007, respectively.

7. Stockholders' Equity

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 the Company's 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 the unamortized balance of $227 for the year ended December 31, 2005 is presented in the recorded accretion table below. The value of the warrants was de minimus.

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 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 year ended December 31, 2005 is presented in the recorded accretion table below.

ELECTRO-OPTICAL SCIENCES, INC.

Notes to Financial Statements — (Continued)

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 Company recorded a beneficial conversion feature of $1,465. The accretion to redemption value of the aforementioned securities is presented in the recorded accretion table below.

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

	Total Amount	Accretion Period in Months	Year Ended December 31, 2005
2003 Series C financing costs	$ 252	60	$ 42
2004 Series C financing costs	448	44	102
Value of Series C warrants	2,643	44	601
Beneficial Conversion — Series C	1,465	44	333
Total	$ 4,808		$ 1,078

During October 2005, the Company completed an initial public offering. The Company issued 4,000,000 shares of the Company's common stock on October 28, 2005 and another 262,300 shares 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 and all related deemed but unpaid dividends on the redeemable convertible preferred stock were forfeited. In addition, the Company issued 1,305,321 shares of the Company's common stock in exchange for 2,610,643 outstanding warrants (a conversion ratio of one share of common stock for two warrants). The Company 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%. 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.

In December 2005, the Company issued a restricted common stock award of 11,488 shares to an employee at the closing market price of the Company's stock on the date of grant, and compensation expense in the amount of $63 for this award was recognized on a straight line basis over the nontransferable period. For the year ended December 31, 2006, $63 was charged to compensation expense.

On October 31, 2006, the Company entered into securities purchase agreements and a registration rights agreement with certain accredited investors for the private placement of 2,312,384 shares of the Company's common stock and warrants to purchase up to 346,857 shares of the Company's common stock for aggregate gross proceeds of approximately $13.2 million and net proceeds of approximately $12.5 million. Pursuant to the securities purchase agreements, for a purchase price of $5.70 each investor received one share of the Company's common stock and a warrant to purchase 0.15 of a share of the Company's common stock. The warrants are five-year warrants with an exercise price of $6.70 per share.

On July 31, 2007, the Company entered into a securities purchase agreement and a registration rights agreement with certain accredited investors for the private placement of 2,000,178 shares of the Company's common stock and warrants to purchase up to 500,041 shares of the Company's common stock for aggregate gross proceeds of approximately $11.5 million and net proceeds of approximately $10.7 million. The private placement closed August 3, 2007. Pursuant to the securities purchase agreement, for a purchase price of $5.75 each investor received one share of the Company's common stock and a warrant to purchase 0.25 of a share of common stock. The warrants are five-year warrants with an exercise price of $8.00 per share.

Both of the private placements were completed pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder.

Pursuant to the terms of the registration rights agreements, the Company filed resale registration statements covering the shares in both private placements, including the shares issuable upon exercise of the warrants, with the SEC. In the unlikely event that the Company fails to meet certain obligations, as described in the registration rights agreements, the holders would be entitled to certain monetary damages.

However, in no event is the Company obligated to make payments in excess of 10% of the aggregate purchase price of the common shares. The Company has concluded that it is unlikely that the Company would be required to remit any payments to its investors for failing to maintain its effectiveness. The Company's resale registration statements on Form S-3 were declared effective by the Securities and Exchange Commission (Registration No. 333-139056 and Registration No. 333-145740) on February 12, 2007 and September 11, 2007, respectively.

As of December 31, 2007, the Company had 10,000,000 shares of $0.10 par value preferred stock authorized and no shares issued and outstanding.

8. Stock-Based Compensation and Warrants:

Stock Options

The Company has one stock option plan which allows 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 awards. The Company also has two other stock-based compensation plans pursuant to which stock options are outstanding but no new grants may be made.

Stock awards under the Company's current plans have been granted at prices which are no less than the market value of the stock on the date of the grant. Options granted under the 2005 Stock Incentive Plan (2005 Plan), are generally time-based or performance-based options and vesting varies accordingly. Options under this plan expire five years from the date of grant. Since the Company adopted the 2005 Plan, awards are not granted under the Company's previous stock option plans; however, additional shares are reserved for issuance pursuant to the 2003 Stock Incentive Plan (2003 Plan) in connection with the formula-based option granted to the Company's CEO, Dr. Joseph Gulfo.

The compensation expense recognized in the Statement of Operations during 2006 and 2007 for stock options and restricted stock awards amounted to $1,036 (of which $487 relates to development milestones) and $577 (of which $312 relates to development milestones), respectively. Cash received from options exercised under all share-based payment arrangements for the years ended December 31, 2006 and 2007 was $88 and $115, respectively.

ELECTRO-OPTICAL SCIENCES, INC.

Notes to Financial Statements — (Continued)

Details regarding the valuation and accounting for stock options are as follows:

The fair value of each option award granted after the adoption of SFAS 123R is estimated on the date of grant using the Black-Scholes option valuation model and assumptions as noted in the following table:

	For The Year Ended	
	December 31, 2006	December 31, 2007
Expected life	5 years	5 years
Expected volatility	60%	60%
Risk-free interest rate	4.92 - 5.04%	3.41 - 5.02%
Dividend yield	0	0

The expected life of the options is based on the observed and expected time to full-vesting, forfeiture and exercise. Groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. The expected volatility is based on implied volatility from other publicly-traded options and other factors. The risk-free interest rate is based on the continuous rates provided by the U.S. Treasury with a term equal to the expected life of the option. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

At December 31, 2007, stock options to purchase 1,812,084 shares of common stock at exercise prices ranging from $.40 to $7.75 per share are outstanding and are exercisable at various dates through 2013. The Company expects that all of these options will vest. The total number of options exercisable at December 31, 2005, 2006, and 2007 was 572,607, 588,284, and 609,901 respectively, with weighted average exercise prices of $1.07, $2.47 and $3.54 respectively.

The status of the Company's stock option plans during the periods indicated is summarized as follows:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2005	965,203	.66		
Granted	212,780	2.43		$ 248
Exercised	(50,881)	.76		
Forfeited or expired	(11,687)	4.85		
Outstanding at December 31, 2005	1,115,415	.95	4.4	4,935
Granted	748,822	5.56	4.1	1,259
Exercised	(135,450)	.65	N/A	730
Forfeited or expired	(39,375)	6.76	N/A	11
Outstanding at December 31, 2006	1,689,412	2.88	4.2	7,331
Granted	277,407	3.11	3.9	456
Exercised	(105,256)	1.09	N/A	558
Forfeited or expired	(49,479)	5.24	N/A	8
Outstanding at December 31,2007	1,812,084	2.96	3.5	4,167
Exercisable at December 31, 2007	609,901	3.54	3.4	1,116

During the year ended December 31, 2006 and 2007 the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was $4.15 and $4.11

respectively per share. The total intrinsic value of options exercised during the years ended December 31, 2006, and 2007 was $730 and $558 respectively. The requisite service periods for options granted during 2006 and 2007 for employees and consultants were four years.

The following table summarizes information about stock options outstanding at December 31, 2007:

	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	923,634	1.7 years	$ .46	171,753	$ .46
$.47-$1.00	119,648	4.4 years	1.00	119,648	1.00
$1.01-$7.75	768,802	3.8 years	6.26	318,500	6.15
$.01-$7.75	1,812,084	3.5 years	$ 2.96	609,901	$ 3.54

As of December 31, 2007, of the total 1,812,084 options outstanding 1,202,183 have not vested. Of this total unvested amount, 1,087,783 will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. Based on 18,340,852 shares outstanding (on a fully-diluted basis) as of December 31, 2007, and assuming such shares remain the total number of shares outstanding on the date we receive PMA approval of MelaFind®, the number of shares subject to Dr. Gulfo's formula-based stock option is 651,881. This stock option vests 50% at the time of PMA approval of MelaFind®, and the remaining 50% in four equal installments over the one-year period following such PMA approval of MelaFind®. As of December 31, 2007, there was $2,858 (of which $2,657 of unrecognized compensation cost relates to development milestones) of total unrecognized compensation cost related to unvested options.

As of December 31, 2007 there were 948,351 shares available for future grants under the Company's 2005 Plan. In addition, the Company has reserved a total of 1,250,000 shares for issuance only pursuant to grants made under the 2003 Plan prior to the adoption of the 2005 Plan. Based on the estimate of the number of shares subject to Dr. Gulfo's formula-based option described above (651,881) and the number of shares subject to other options granted under the 2003 Plan (405,441), 192,678 shares out of the total of 1,250,000 shares reserved for issuance under the 2003 Plan are available for issuance; however, such shares are only available for issuance pursuant to Dr. Gulfo's formula-based stock option.

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.

Pursuant to a consulting agreement, upon the closing of the initial public offering, the Company issued an option to purchase 50,000 shares of common stock with an exercise price equal to the initial public offering price of $5.00 to a member of the Company's Board of Directors. The Company recognized compensation expense of $138 during the year ended December 31, 2005, as these options vested immediately.

On March 24, 2006, the Company issued to its then acting Chief Operating Officer and a member of the Board, Dr. Gerald Wagner, stock option grants of 49,500 shares of the Company's common stock which vested immediately and 50,000 shares which vested upon commencement of the pivotal trial for MelaFind®. Compensation expense of $162 was charged to operations in 2006. With the start of the clinical trials in late January 2007, the Company recorded a $140 charge to operations in the first quarter of 2007.

On April 24, 2006, the Company entered into an agreement with the Company's Vice-President of Finance and Chief Financial Officer. In accordance with that agreement a five year option under the Company's 2005 Plan to purchase up to 100,000 shares of the Company's common stock at $5.82 per share was granted.

On May 22, 2006, the Company's Vice-President — Corporate Secretary and the Company's Vice-President of Marketing and Sales were granted additional five year options to purchase 7,500 and 5,000 shares, respectively, at $7.08 per share.

On May 29, 2006, the Company entered into an agreement with the Company's Vice-President of Technical Support. In accordance with that agreement, a five year option under the Company's 2005 Plan to purchase up to 40,000 shares of the Company's common stock at $7.60 per share was granted. On November 29, 2007 the VP of Technical Support was granted an additional five year option under the Company's 2005 Plan to purchase up to 10,000 shares of the Company's common stock at $4.50 per share.

On December 1 2006, 5,000 options to acquire shares of the Company's common stock at $7.75 were granted to each of the six non-employee members of the Company's Board of Directors under the Company's 2005 Plan. These five-year options vested December 1, 2007.

On November 30, 2007, 5,000 options to acquire shares of the Company's common stock at $4.92 were granted to each of the six non-employee members of the Company's Board of Directors under the Company's 2005 Plan. These five-year options to purchase the Company's common stock vest one year from the date of grant.

Subsequent to the end of the 2007 fiscal year, on February 11, 2008, the Company entered into an agreement with the Company's Vice-President of Commercialization. In accordance with that agreement a five year option under the Company's 2005 Plan to purchase up to 80,000 shares of the Company's common stock at $4.40 per share was granted on February 25, 2008.

Warrants

Warrants outstanding at December 31, 2007 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 7-year warrants to purchase 54,988 shares of the Company's Series C redeemable convertible 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 54,988 shares of the Company's common stock.

In connection with the Company's initial public offering in October 2005, the Company issued 150,000 warrants to the underwriters to purchase shares of the Company's common stock at $6.25 per share. These 5-year warrants became exercisable on October 28, 2006.

In addition, as previously discussed, in connection with the Company's private placements in November 2006 and August 2007, the Company issued warrants to purchase up to 346,857 and 500,041 shares, respectively, of the Company's common stock. The warrants are exercisable for five years at a price of $6.70 and $8.00 per share, respectively.

9. Related Party Consulting Agreements (see Note 5):

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 $26

in 2005 and $29 in 2006 and $24 in 2007. This consulting agreement is terminable by either party on 30 days' written notice.

Consulting Agreement with Marek Elbaum, Ph.D.

During January 2004, the Company amended its employment agreement with Marek Elbaum, Ph.D, 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 which superseded the amended employment agreement. In consideration of the services as Chief Scientist to be provided, the Company agreed to pay Dr. Elbaum a monthly fee of $15. The term of this agreement extended for a period of two years and was 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, the Company agreed to pay to Dr. Elbaum a termination fee of $100. Dr. Elbaum and the Company entered into an amended agreement effective June 1, 2007. Under the terms of the amended agreement, Dr. Elbaum will be paid a monthly fee of $9 through January 2009.

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 the Company's 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 amounts paid to Dr. Friedman amounted to $30 in 2005, $42 in 2006 and $58 in 2007.

Consulting Agreement with Gerald Wagner, Ph.D. (see also Note 8)

On March 24, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D., a member of the Company's Board of Directors and its former acting Chief Operating Officer. The effective date of this amended and restated agreement was April 1, 2006. Under this amended consulting agreement, the Company agreed to pay Dr. Wagner the annual amount of $180 payable monthly over the term of the agreement. 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 vested upon commencement of the pivotal trial for Melafind® in January 2007. In addition, on March 24, 2006, Dr. Wagner received another stock option grant of 49,500 shares of the Company's common stock which vested immediately.

With the start of our pivotal clinical trial in January 2007, Dr. Wagner transitioned out of his role as our acting Chief Operating Officer and entered into an amended and restated consulting contract with the Company. Under the terms of the amended contract, Dr. Wagner is paid a monthly retainer of $2.5 and will be paid $2.5 for each additional consulting day. This amended agreement will end at the option of Dr. Wagner or the Company at any time, by providing fifteen days prior written notice, or immediately upon the mutual agreement of the Company and Dr. Wagner. For the year ended December 31, 2007, the Company paid consulting costs totaling $27.5 under this amended contract and $15 covering January as acting Chief Operating Officer under the previous consulting agreement.

10. Other Income (including gain on sale of discontinued operations):

On March 28, 2007, the Company announced the signing of an agreement with L'Oreal to study the feasibility of using the Company's novel multi-spectral imaging technology for the evaluation and differentiation of pigmented skin lesions of cosmetic importance. EOS has granted L'Oreal an option to take an

exclusive license to use EOS technology in the field covered by the research, on terms to be mutually agreed. The option expires on the earlier to occur of six months after the completion of the Feasibility Plan, as defined in the agreement, or August 28, 2008. The laboratory and clinical research will be funded by L'Oreal. Pursuant to the agreement, L'Oreal is responsible for all costs and expenses incurred in connection with the Feasibility Program, and will reimburse EOS for expenses incurred by EOS with respect to the Feasibility Program. During the year ended December 31, 2007, the Company earned $59, recorded as other income, to offset expenses incurred by EOS under the Feasibility Program with L'Oreal. Amounts received from L'Oreal in advance of being earned have been recorded as deferred income at December 31, 2007.

Effective April 5, 2005, the Company decided to discontinue all operations associated with its DIFOTI® product, in order to focus its resources and attention on the development and commercialization of MelaFind®. In accordance with the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets," the results of operations of the DIFOTI® business for the current and prior periods have been excluded from continuing operations and have been reported as discontinued operations. During December 2006, the Company entered into a sale and exclusive licensing agreement with KaVo, a leading dental equipment manufacturer, which provides for KaVo to further develop and commercialize DIFOTI®. Upon execution of the agreement, KaVo paid the Company $500, and made a second payment of $500 in July 2007. Beginning in 2008, KaVo is required to pay to the Company a royalty stream based upon the worldwide aggregate net sales of the licensed product, as defined in the license agreement, or a set minimum royalty payment, whichever is greater. Royalties, if any, will be recorded when earned.

For the year ended December 31, 2006 the Company recorded a gain of $781 on the sale and licensing of its remaining DIFOTI® assets based upon the cash proceeds and the discounted value of the second payment.

For the year ended December 31, 2007, there was a gain of $28 on the sale of discontinued operations. Costs associated with the 2006 transaction with KaVo were lower than expected and the December 31, 2006 accrual to capture these expenses was partially reversed in 2007.

Losses attributable to DIFOTI® operations discontinued in April 2005 amounted to $442 for the year ended December 31, 2005.

11. Income Taxes:

Because the Company incurred net losses, it did not provide for income taxes for the years ended December 31, 2005, 2006 and 2007.

The difference between the actual income tax benefit and that computed by applying the U.S. federal income tax rate of 34% to pretax loss from continuing operations is summarized below:

	Year Ended December 31,		
	2005	2006	2007
Computed expected tax benefit	$ (2,136)	$ (3,866)	$ (4,068)
State tax benefit, net of federal effect	(377)	(682)	(718)
Valuation allowance	2,513	4,548	4,786
Provision for income taxes	$ —	$ —	$ —

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities as of December 31, 2006 and 2007 are as follows:

	December 31,	
	2006	2007
Deferred tax assets:		
Net operating loss carryforwards	$ 6,621	$ 8,409
Capitalized research and developmental costs	4,252	7,094
Non-cash compensation	919	1,064
Total deferred tax assets	11,792	16,567
Less valuation allowance	(11,792)	(16,567)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based on the Company's historical net losses, management does not believe that it is more likely than not that the Company will realize the benefits of these deferred tax assets and, accordingly, a full valuation allowance has been recorded against the deferred tax assets as of December 31, 2006 and 2007. The Company's valuation allowance against its deferred tax assets increased by $2,691, $4,236 and $4,775 for the years ended December 31, 2005, 2006 and 2007, respectively.

The Company has net operating loss carryforwards of approximately $16,567 to offset future taxable income. The Company has experienced certain ownership changes, which under the provisions of Section 382 of the Internal Revenue Code of 1986, as amended, result in annual limitations on the Company's ability to utilize its net operating losses in the future. The Company has conducted a study to determine the extent of the limitations. Based on the study, the Company believes that these limitations will not materially impact the Company's ability to utilize its net operating losses in the future.

In July 2006, the FASB issued Interpretation No. 48, "Uncertainty in Income Taxes" ("FIN 48"). FIN 48 applies to all tax positions and clarifies the recognition of tax benefits in the financial statements by providing for a two-step approach of recognition and measurement. The first step involves assessing whether the tax position is more likely than not to be sustained upon examination based upon its technical merits. The second step involves measurement of the amount to recognize. Tax positions that meet the more likely than not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate finalization with the taxing authority. The Company adopted FIN 48 effective January 1, 2007. The adoption of FIN 48 did not have a material impact on the Company's consolidated results of operations and financial position.

ELECTRO-OPTICAL SCIENCES, INC.

Notes to Financial Statements — (Continued)

12. Quarterly Operating Results (Unaudited)

The following is a summary of operating results by quarter for the years ended December 31, 2007 and 2006:

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2007				
Loss from continuing operations	$ (2,994)	$ (3,096)	$ (2,709)	$ (3,166)
Gain on sale of discontinued operations				$ 28
Net Loss	$ (2,994)	$ (3,096)	$ (2,709)	$ (3,138)
Net loss attributable to common stockholders	$ (2,994)	$ (3,096)	$ (2,709)	$ (3,138)
Basic and diluted net loss per share of common stock	$ (0.22)	$ (0.23)	$ (0.18)	$ (0.20)
2006				
Loss from continuing operations	$ (2,889)	$ (2,928)	$ (2,425)	$ (3,130)
Gain on sale of discontinued operations				$ 781
Net Loss	$ (2,889)	$ (2,928)	$ (2,425)	$ (2,349)
Net loss attributable to common stockholders	$ (2,889)	$ (2,928)	$ (2,425)	$ (2,349)
Basic and diluted net loss per share of common stock	$ (0.27)	$ (0.27)	$ (0.22)	$ (0.18)

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

Our company's management, with the participation of our chief executive officer and our chief financial officer, has evaluated the effectiveness of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities and Exchange Act of 1934) as of December 31, 2007.

Based on such evaluation, our chief executive officer and our chief financial officer have concluded that, as of December 31, 2007, our disclosure controls and procedures were effective to ensure that the information we are required to disclose in reports that we file or submit to the SEC is (1) recorded, processed, summarized and reported within the time periods specified under the rules and forms of the SEC and (2) accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

Report of Management on Internal Control Over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. Under the rules of the SEC,"internal control over financial reporting procedures" is defined as a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Internal control over financial reporting includes maintaining records, that in reasonable detail, accurately and fairly reflect our transactions and our dispositions of assets; provide reasonable assurance that transactions are recorded as necessary for preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America; provide reasonable assurance that receipts and expenditures of company assets are made only in accordance with management authorization; and provide reasonable assurance regarding the prevention or the timely detection of the unauthorized acquisition, use or disposition of company assets that could have a material effect on our financial statements. Because of its inherent limitations, internal control over financial reporting may not provide absolute assurance that a misstatement of our financial statements would be prevented or detected.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control — Integrated Framework*. Based on this evaluation, management concluded that the company's internal control over financial reporting was effective as of December 31, 2007.

Eisner LLP, the independent registered public accounting firm, have issued their report on the effectiveness of our internal control over financial reporting as of December 31, 2007. Their report is included in this Item 9A.

Report of Independent Registered Public Accounting Firm

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

We have audited Electro-Optical Sciences, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Report of Management on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Electro-Optical Sciences, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Electro-Optical Services, Inc. as of December 31, 2006 and December 31, 2007, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2007, and our report dated March 10, 2008 expressed an unqualified opinion on those financial statements.

/s/ Eisner LLP

New York, New York
March 10, 2008

Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2007 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, Executive Officers, and Corporate Governance***

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, 2007, 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 and Related Stockholder Matters,***

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, and Director Independence***

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)
4.3	Form of Warrant.(7)
4.4	Form of Warrant.(13)
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)
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.(11)
10.18*	Resignation Agreement, dated April 24, 2006, between the Registrant and Karen Krumeich.(5)
10.19*	Employment Offer Letter, dated April 24, 2006, between the Registrant and Richard I. Steinhart.(5)
10.20*	Employment Offer Letter, dated May 30, 2006, between the Registrant and Christiano S. Butler.(6)
10.21	Securities Purchase Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of October 31, 2006.(8)
10.22	Securities Purchase Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of October 31, 2006.(8)
10.23	Registration Rights Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of October 31, 2006.(8)
10.24	Placement Agency Agreement by and between the Registrant and Jefferies & Company, Inc., dated as of October 31, 2006.(7)
10.25	Licensing Agreement between the Registrant and KaVo Dental GmbH, dated as of December 5, 2006.(9)

Exhibit Number	Exhibit Title
10.26*	Amendment No. 1 to Amended and Restated Consulting Agreement dated as of January 30, 2007 by and among the Registrant, Gerald Wagner and Gerald Wagner Consulting LLC.(10)
10.27	Research and Feasibility Agreement between Registrant and L'Oreal S.A. dated as of March 26, 2007.(12)
10.28	Securities Purchase Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of July 31, 2007.(13)
10.29	Registration Rights Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of July 31, 2007.(13)
10.30	Fifth Amendment dated as of August 24, 2007, by and between the Registrant and Bridge Street Commercial, LLC, for office space located at 1 Bridge Street, Irvington, New York.(14)
21.1#	Subsidiaries of Registrant.
23.1#	Consent of Eisner LLP
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#	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted 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.

(5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 27, 2006.

(6) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on June 2, 2006.

(7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 1, 2006.

(8) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 8, 2006.

(9) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 11, 2006.

(10) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 31, 2007.

(11) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed on March 29, 2006.

(12) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on March 28, 2007.

(13) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on August 1, 2007.

(14) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2007.

\# 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.

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

Dated: March 12, 2008

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 12, 2008
/s/ Richard I. Steinhart **Richard I. Steinhart**	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2008
/s/ Breaux Castleman **Breaux Castleman**	Chairman of the Board of Directors	March 12, 2008
/s/ Sidney Braginsky **Sidney Braginsky**	Director	March 12, 2008
/s/ George C. Chryssis **George C. Chryssis**	Director	March 12, 2008
/s/ Martin D. Cleary **Martin D. Cleary**	Director	March 12, 2008
/s/ Dan W. Lufkin **Dan W. Lufkin**	Director	March 12, 2008
/s/ Gerald Wagner, PhD. **Gerald Wagner, PhD.**	Director	March 12, 2008

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

The Registrant does not have any subsidiaries.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements of Electro-Optical Sciences, Inc. on Forms S-3 (File No. 333-139056 and File No. 333-145740) and on Form S-8 (File No. 333-136183) of our reports dated March 10, 2008 with respect to our audits of the balance sheets of Electro-Optical Sciences, Inc. as of December 31, 2006 and 2007, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2007, and our audit of the effectiveness of internal control over financial reporting as of December 31, 2007, which reports appear in the December 31, 2007 annual report on Form 10-K of Electro-Optical Sciences, Inc. We also consent to the reference to our firm under the heading "Experts" in the Registration Statements on Forms S-3 (Registration No. 333-139056 and File No. 333-145740).

/s/ Eisner, LLP

New York, NY
March 10, 2008

Exhibit 31.1

CERTIFICATION

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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;

d) 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, M.D.
Joseph V. Gulfo, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 12, 2008

Exhibit 31.2

CERTIFICATION

I, Richard I. Steinhart, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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;

d) 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/ Richard I. Steinhart

Richard I. Steinhart
Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Date: March 12, 2008

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
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, 2007 (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, M.D.
Joseph V. Gulfo, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

March 12, 2008

/s/ Richard I. Steinhart
Richard I. Steinhart
Vice President & Chief Financial Officer
(Principal Accounting and Financial Officer)

March 12, 2008

* 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.