0

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

**FORM 10-Q** 

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

For the quarterly period ended September 30, 2008

to

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

For the transition period from

Commission file number 000 — 51481

# **ELECTRO-OPTICAL SCIENCES, INC.**

(Exact name of Registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

3 West Main Street, Suite 201 Irvington, New York

(Address of Principal Executive offices)

13-3986004 (I.R.S. Employer Identification No.)

> **10533** (Zip Code)

# Registrant's Telephone Number, including area code: (914) 591-3783

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.

# 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):

Yes 🗹 o

Large accelerated filer o

Accelerated filer 🗹

Non-accelerated filer o (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No 🗹

As of November 4, 2008, 17,634,498 shares of the Registrant's common stock were outstanding.

Smaller reporting company o

# Electro-Optical Sciences, Inc. Table of Contents

PART I. FINANCIAL INFORMATION	Page
ITEM 1. Financial Statements	
Condensed Balance Sheets as of September 30, 2008 (unaudited) and December 31, 2007	2
Condensed Statements of Operations (unaudited) for the three and nine month periods ended September 30, 2008 and 2007	3
Condensed Statements of Cash Flows (unaudited) for the nine month periods ended September 30, 2008 and 2007	4
Notes to Condensed Financial Statements (unaudited)	5
ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	16
ITEM 3. Quantitative and Qualitative Disclosures about Market Risk	24
ITEM 4. Controls and Procedures	24
PART II. OTHER INFORMATION	
ITEM 1. Legal Proceedings	25
ITEM 1A. Risk Factors	25
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds	33
ITEM 3. Defaults Upon Senior Securities	33
ITEM 4. Submission of Matters to a Vote of Security Holders	33
ITEM 5. Other Information	33
ITEM 6. Exhibits	34
SIGNATURES	37
EXHIBIT INDEX EX-31.1: CERTIFICATION EX-31.2: CERTIFICATION	38
EX-32.1: CERTIFICATION	

# ELECTRO-OPTICAL SCIENCES, INC. CONDENSED BALANCE SHEETS

	September 30, 2008 (unaudited)	December 31, 2007 *
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 18,775,788	\$ 19,196,589
Marketable securities	795,276	1,719,905
Prepaid expenses and other current assets	148,482	411,554
Total Current Assets	19,719,546	21,328,048
Property and equipment, net	706,492	616,110
Patents and trademarks, net	100,664	118,138
Other assets	45,876	45,876
Total Assets	\$ 20,572,578	\$ 22,108,172
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,021,062	\$ 567,987
Accrued expenses (includes related parties of \$17,500 as of September 30, 2008 and \$10,000 as of December 31, 2007)	906,922	674,711
Deferred income	2,085	74,946
Other current liabilities	27,446	18,804
Total Current Liabilities	1,957,515	1,336,448
COMMITMENTS AND CONTINGENCIES (Note 9)		
Stockholders' Equity		
Preferred stock — \$.10 par value; authorized 10,000,000 shares; none issued and outstanding at September 30, 2008 and at December 31, 2007		
Common stock — \$.001 par value; authorized 30,000,000 shares; issued and outstanding 17,551,745 shares at		
September 30, 2008 and 15,401,882 at December 31, 2007	17,552	15,402
	EE 100 GE 1	60.000.000

September 30, 2008 and 15,401,882 at December 31, 2007	17,552	15,402
Additional paid-in capital	75,189,654	63,930,689
Accumulated comprehensive loss	(1,899)	(12,136)
Accumulated deficit	(56,590,244)	(43,162,231)
Stockholders' Equity	18,615,063	20,771,724
Total Liabilities and Stockholders' Equity	\$ 20,572,578	\$ 22,108,172

\* Derived from the audited balance sheet as of December 31, 2007

See accompanying notes to the financial statements

# ELECTRO-OPTICAL SCIENCES, INC. CONDENSED STATEMENTS OF OPERATIONS (unaudited)

	Three months ended September 30,		Nine months ende	
	2008	2007	2008	2007
Operating expenses:				
Research and development	\$ 3,325,122	\$ 1,810,866	\$ 9,994,205	\$ 5,649,925
General and administrative	1,043,111	1,217,993	3,957,585	3,968,355
Operating loss	(4,368,233)	(3,028,859)	(13,951,790)	(9,618,280)
Interest income	105,569	279,523	380,167	778,732
Royalty income	5,000		5,000	
Other income	57,752	40,335	138,610	40,335
Net loss	(4,199,912)	\$ (2,709,001)	(13,428,013)	\$ (8,799,213)
Basic and diluted net loss per common share	\$ (0.25)	\$ (0.18)	\$ (0.85)	\$ (0.64)
Basic and diluted weighted average number of common shares				
outstanding	16,678,852	14,684,427	15,832,391	13,822,333

See accompanying notes to the financial statements

# ELECTRO-OPTICAL SCIENCES, INC. CONDENSED STATEMENTS OF CASH FLOWS (unaudited)

	Nine Months Ended September 30,	
	2008	2007
Cash flows from operating activities:	¢ (10, 400, 040)	¢ (0 500 010)
Net loss	\$(13,428,013)	\$ (8,799,213)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	225,825	163,198
Noncash compensation	248,140	489,923
Amortization of unearned interest income — discontinued operations		(12,320)
Amortization of discount on marketable securities	519	(56)
Changes in operating assets and liabilities:		
Increase in other assets		(5,518)
Decrease in prepaid expenses and other current assets	263,072	43,274
Decrease in deferred income	(72,861)	
Increase (decrease) in accounts payable and accrued expenses	685,286	(219,236)
Increase (decrease) in other current liabilities	8,642	(3,784)
Net cash used in operating activities	(12,069,390)	(8,343,732)
Cash flows from investing activities:		
Patent costs		(39,321)
Purchases of property and equipment	(298,733)	(220,500)
Proceeds from sale of discontinued operations		500,000
Sale (purchase) of marketable securities	934,347	(399,500)
Net provided by (cash used) in investing activities	635,614	(159,321)
Cash flows from financing activities:		
Proceeds from sale of stock — financing	11,909,057	11,501,023
Expenses related to sale of stock — financing	(941,438)	(779,866)
Proceeds from exercise of stock options	34,770	114,527
Proceeds from exercise of stock warrants	10,586	
Net cash provided by financing activities	11,012,975	10,835,684
Net increase (decrease) in cash and cash equivalents	(420,801)	2,332,631
Cash and cash equivalents at beginning of period	19,196,589	20,939,527
Cash and cash equivalents at end of period	\$ 18,775,788	\$23,272,158

See accompanying notes to the financial statements

# ELECTRO-OPTICAL SCIENCES, INC. NOTES TO CONDENSED FINANCIAL STATEMENTS (In thousands, except for share and per share data) (unaudited)

# 1. ORGANIZATION AND BASIS OF PRESENTATION

Electro-Optical Sciences, Inc., a Delaware corporation ("EOS" or 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 accrual phase of the MelaFind® pivotal trial concluded at the end of July 2008. Follow-up and data analysis is ongoing and will continue through the fourth quarter of 2008. The results of the trial are expected to be available later in the fourth quarter. If the pivotal trial results and FDA approval process proceed as anticipated, management believes that PMA approval could come as early as the middle of 2009.

To date the Company has not generated any revenues from MelaFind<sup>®</sup>. All of the Company's historical revenues came from activities and products that have since been discontinued, including our DIFOTI<sup>®</sup> product, a non-invasive imaging device for the detection of dental cavities. The Company discontinued all operations associated with its DIFOTI<sup>®</sup> product effective as of April 5, 2005 in order to focus its resources on the development and commercialization of MelaFind<sup>®</sup>. As more fully described in Note 13, in December 2006, the Company sold and licensed its rights to the DIFOTI<sup>®</sup> assets and does not expect to have any significant continuing responsibility for the DIFOTI<sup>®</sup> business or products.

The Company anticipates that it will continue to incur net losses for the foreseeable future in the development and commercialization of the Melafind<sup>®</sup> device. From inception, the Company 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, two private placements: (one that closed in November 2006 and a second that closed in August 2007 and a registered direct offering which closed August 8, 2008 (refer to Note 10 for further details).

As of September 30, 2008, the total of cash, cash equivalents and marketable securities was \$19.6 million, which management anticipates will allow the Company to fund anticipated levels of operations into 2010. The Company will require additional funds to achieve significant commercialization of MelaFind<sup>®</sup>. However, there can be no assurances that the Company will be able to raise additional capital in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term.

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 intellectual property rights, competition, rapid technological change, government regulations, changing health care marketplace, recruiting and retaining key personnel, and reliance on third party manufacturing organizations.

The unaudited condensed financial statements included herein have been prepared from the books and records of the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for reporting on Form 10-Q. The information and note disclosures normally included in complete financial statements prepared in accordance with generally accepted accounting principles in the United States ("GAAP") have been condensed or omitted pursuant to such rules and regulations. The interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007.

The Company's management is responsible for the financial statements included in this document. The Company's interim financial statements are unaudited. Interim results may not be indicative of the results that may be expected for the year. However, the Company believes all adjustments considered necessary for a fair presentation of these interim financial statements have been included and are of a normal and recurring nature.

#### 2. MARKETABLE SECURITIES

The Company's marketable securities consist of corporate debt securities with a weighted average maturity not in excess of twelve months. The Company classifies its marketable securities as available-for-sale, as defined by Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of stockholders' equity in accumulated other comprehensive loss. Interest income, realized gains and losses, and declines in value of securities judged to be other-than-temporary are included in the Company's statement of operations. As of September 30, 2008, marketable securities consisted of:

_	September 30, 2008			
	Fair V	alue	Unrealized Gain (Loss)	
Ģ	\$	795	\$ 2	

#### Corporate debt securities

The Company evaluates declines in the fair value of its investments in available-for-sale marketable securities to determine if these declines are other-thantemporary. 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.

# **3. 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 are reflected as accumulated comprehensive loss in stockholders' equity on the Company's balance sheet. For the three months ended September 30, 2008, comprehensive loss was \$4,199 which includes a net loss of \$4,200 and an unrealized gain on available-for-sale marketable securities of \$1. For the nine months ended September 30, 2008, comprehensive loss was \$13,418, which includes a net loss of \$13,428 and an unrealized gain on available-for-sale marketable securities of \$10. For the nine months ended September 30, 2007, comprehensive loss was \$8,806, which includes a net loss of \$8,799 and an unrealized loss on available-for-sale marketable securities of \$7.

# 4. USE OF ESTIMATES

The preparation of financial statements in conformity with GAAP 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.

# 5. RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In February 2007, the Financial Accounting Standards Board ("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 the 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 adoption of SFAS No. 159 did not have a material impact on the Company's 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 relating to financial assets is effective for financial statements issued for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 did not have a material impact on the Company's financial statements. The provisions of SFAS 157 related to other non-financial assets and liabilities will be effective for the Company on January, 1, 2009, and will be applied prospectively. The Company is currently evaluating the impact that these additional SFAS 157 provisions will have on the Company's financial statements.

In October 2008, the FASB issued FSP FAS No. 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active." The FSP clarifies the application of SFAS No. 157, "Fair Value Measurements," when the market for a financial asset is not active. The FSP was effective upon issuance, including reporting for prior periods for which financial statements have not been issued. The adoption of the FSP for reporting as of September 30, 2008 did not have a material impact on the Company's financial statements.

## 6. RECENT ACCOUNTING DEVELOPMENTS

In March 2008, the FASB issued SFAS No. 161 "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS 161"). This new standard enhances disclosure requirements for derivative instruments in order to provide users of financial statements with an enhanced understanding of (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" and its related interpretations, and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is to be applied prospectively for the first annual reporting period beginning on or after November 15, 2008. The Company believes that the adoption of SFAS 161 will not have a material impact on the Company's financial statement disclosures since the Company does not currently have any derivative instruments.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations ("SFAS 141R"). SFAS 141R replaces FASB SFAS No. 141, and 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 non-controlling interest in the acquired company. 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. SFAS 141R 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. The Company believes the adoption of this pronouncement will not have a material impact on the Company's financial statements.

In December 2007, the FASB issued SFAS No. 160, Non-controlling Interests in Consolidated Financial Statements—an amendment of ARB No. 51 ("SFAS 160"). SFAS 160 amends ARB 51 to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling 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, SFAS 160 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 SFAS 160 was issued. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The Company believes the adoption of this pronouncement will not have a material impact on the Company's financial statements.

In April 2008, the FASB issued FSP FAS No. 142-3, "Determination of the Useful Life of Intangible Assets." The FSP amends the factors an entity should consider in developing renewal or extension assumptions used in determining the useful life of recognized intangible assets under SFAS No. 142, "Goodwill and Other Intangible Assets." The FSP must be applied prospectively to intangible assets acquired after the effective date. The Company will apply the guidance of the FSP to intangible assets acquired after January 1, 2009.

# 7. NET LOSS PER COMMON SHARE

Net loss per common 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 net 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 the 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:

	Septer	nber 30,
	2008	2007
Common stock options	1,949,616	1,776,418
Warrants	1,124,544	1,126,886
Total	3,074,160	2,903,304

# 8. STOCK-BASED COMPENSATION

The Company has one stock-based compensation plan which allows the Board of Directors to grant incentives to employees, consultants, directors, officers 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.

The Company records compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), as interpreted by SEC Staff Accounting Bulletin No. 107. The Company has adopted the modified prospective transition method provided for under SFAS 123R. Under this transition method, compensation cost associated with stock options recognized in the three and nine month periods ended September 30, 2008 and 2007 includes: (1) amortization related to the remaining unamortized 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. For performance-based grants, a compensation charge is recorded when it is probable that performance or service 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.

The compensation expense recognized in the Statement of Operations in the third quarter of 2008 and 2007 for stock options amounted to \$69 (of which \$20 relates to performance milestones) and \$110 (of which \$48 relates to performance milestones), respectively. For the nine months ended September 30, 2008 and 2007, compensation expense totaled \$249 (of which \$73 relates to performance milestones) and \$490 (of which \$279 relates to performance milestones), respectively. Cash received from options and warrants exercised under all share-based payment arrangements for the three months ended September 30, 2008 and 2007 were \$21 and \$0, respectively, and for the nine month periods ended September 30, 2008 and 2007, \$35 and \$114, respectively.



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 Nine Months Ended September 30, 2008	For the Nine Months Ended September 30, 2007
Expected life	5 years	5 years
Expected volatility	60%	60%
Risk-free interest rate	2.95-3.72%	4.51-5.02%
Dividend yield	0%	0%

The expected life of the options is based on the observed and expected time to post-vesting, forfeiture and exercise. Groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. The expected volatility is calculated on closing price volatility based on daily closing prices from the Company's initial public offering ("IPO") to September 30, 2008, which approximates implied volatility from other publicly-traded stock that was established at the time of our IPO. 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.

Stock awards under the Company's current plans are granted at prices which are no less than the market value of the stock on the date of grant. Options granted under the 2005 Stock Incentive Plan ("2005 Plan") are generally time-based or performance-based options, and vesting varies accordingly. Options granted under this plan as of September 30, 2008 expire five years from the date of grant.

The status of the Company's stock option plans at September 30, 2008 is summarized in the following:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,812,084	\$2.96	3.5	
Granted	220,039	\$3.00	2.7	—
Exercised	(59,070)	0.59		
Forfeited or expired	(23,437)	\$2.54	—	_
Outstanding at September 30, 2008	1,949,616	\$3.04	2.1	\$5,158
Vested and exercisable at September 30, 2008	633,056	\$3.91	2.3	\$1,200

		Options Outstanding Weighted-		Options Exe	rcisable
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted- Average Exercise Price
\$.01-\$.46	955,036	1.1 years	\$.46	151,753	\$.46
\$.47-\$1.00	105,578	3.2 years	\$1.00	105,578	\$1.00
\$1.01-\$7.75	889,002	3.1 years	\$6.05	375,725	\$6.12
\$.01-\$7.75	1,949,616	2.1 years	\$3.04	633,056	\$3.91



During the three months and nine months ended September 30, 2008, the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was \$5.57 and \$3.87, respectively. For the three and nine month periods ended September 30, 2007, the weighted average fair value of options granted was \$6.28 and \$4.55, respectively. For the three and nine months ended September 30, 2008, the total intrinsic value of options exercised was \$266 and \$384, respectively. For the three and nine months ended September 30, 2007, the total intrinsic value of options exercised was \$0 and \$558, respectively.

Since the Company adopted the 2005 Plan, the Company has ceased granting awards 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 a formula-based option granted to the Company's CEO, Dr. Joseph Gulfo (refer to Note 14 for further details).

As of September 30, 2008, of the total 1,949,616 options outstanding, 1,316,560 have not vested. Of this total unvested amount, 1,187,685 will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. Based on 20,625,905 shares outstanding (on a fully-diluted basis) as of September 30, 2008, and assuming such shares remain the total number of shares outstanding on the date the Company receives PMA approval of MelaFind®, the number of shares subject to Dr. Gulfo's formula-based stock option is 743,283. This formula-based 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 September 30, 2008, there was \$3,439 of total unrecognized compensation cost related to unvested options to be recognized over a period to be determined by milestones.

As of September 30, 2008, there were 828,151 shares available for future grants under the Company's 2005 Plan. In addition, 116,276 shares are reserved under the 2003 Plan for future allocation to Dr. Gulfo in accordance with the provisions of his formula-based stock option.

As more fully explained in Note 14, on October 10, 2008, Dr. Gulfo's formula-based stock option was cancelled and the Board of Directors of the Company granted Dr. Gulfo new stock options.

# 9. COMMITMENTS AND CONTINGENCIES

The Company is party to 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 under these leases are due as follows:

2008	2009	2010	2011
\$81	\$ 256	\$ 186	\$ 16

During March 2007, the Company entered into an agreement with L'Oreal to study and assess the feasibility of using EOS' 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 was set to expire on the earlier to occur of six months after the completion of the Feasibility Plan, as defined in the agreement, or August 31, 2008. The Company and L'Oreal have mutually agreed to extend the period of this option until June 30, 2009. The laboratory and clinical research is being 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 three and nine month periods ended September 30, 2008, the Company earned \$45 and \$97, respectively from L'Oreal as other income to offset expenses incurred by EOS under the feasibility program. \$40 was earned during the three and nine months ended September 30, 2007.

In August of 2006, the Company engaged Carl Zeiss Jena GmbH on usual commercial terms to build the lenses and assemblies, as well as provide certain technical consulting services for the MelaFind<sup>®</sup> units which have been used in the Company's pivotal clinical trial. The Company expects Carl Zeiss Jena GmbH to continue to supply lenses and assemblies throughout 2008.

In January 2006, the Company entered into an agreement with ASKION GmbH ("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 data collection sites in the United States and Europe. The Company is required to make payments to ASKION upon delivery of the MelaFind® systems. The Company expects to maintain a relationship, which has evolved into a month-to-month agreement, with ASKION and continue with production and development activities throughout 2008.

The Company has an employment agreement with its President and Chief Executive Officer, Dr. Gulfo, which provides for an annual base salary, stock options and discretionary performance bonuses. The agreement, which provides for automatic one-year renewal terms, currently runs through the end of 2008. Effective March 1, 2008, the Board of Directors increased Dr. Gulfo's annual base salary to \$280 and awarded him a bonus of \$65.

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.

# **10. STOCKHOLDERS' EQUITY**

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. The private placement closed November 3, 2006. The private placement was completed pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder.

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. The private placement was completed pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, and 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 deadlines, 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 Forms S-3 were declared effective by the SEC (file #333-139056 and file #333-145740) on February 12, 2007 and September 11, 2007, respectively.

On June 26, 2008, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed \$40 million. The SEC declared the registration statement effective on July 7, 2008 (file# 333-151935). Management utilized this shelf registration statement to raise additional equity capital by completing a registered direct offering of 2,088,451 shares of the Company's common stock for aggregate gross proceeds of approximately \$11.9 million (\$11 million approximate net proceeds to the Company) at a per

share offering price of \$5.68. The offering closed August 8, 2008. The Company will require additional funds to achieve significant commercialization of MelaFind<sup>®</sup>. However, there can be no assurances that the Company will be able to raise additional capital in the future. The proceeds from this offering combined with existing cash balances will allow the Company to fund anticipated levels of operations into 2010. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term.

# **11. WARRANTS**

Warrants outstanding at September 30, 2008 include a five-year warrant to purchase 75,000 shares of the Company's common stock at an exercise price of \$7.00 per share issued to one of the Company's consultants in 2004, and seven-year warrants to purchase an aggregate of 52,646 shares the Company's common stock at an exercise price of \$4.52 per share issued in connection with the sale of Series C redeemable convertible preferred stock.

In connection with the Company's IPO which closed on November 2, 2005, the Company issued 150,000 warrants to the underwriters to purchase shares of the Company's common stock at \$6.25 per share, which became exercisable commencing October 28, 2006, and have a five-year term.

Additionally, as previously discussed, in connection with the Company's two private placement financings the following warrants have been granted and remain outstanding as of September 30, 2008:

- Financing that closed November 3, 2006: warrants to purchase up to 346,857 shares of the Company's common stock were issued. The warrants are fiveyear warrants with an exercise price of \$6.70 per share,
- Financing that closed August 3, 2007: warrants to purchase up to 500,041 shares of the Company's common stock were issued. The warrants are five-year warrants with an exercise price of \$8.00 per share.

Cash received from warrants exercised for both the three months and nine months ended September 30, 2008 and 2007 were \$11 and \$0, respectively.

# **12. RELATED PARTY CONSULTING AGREEMENTS**

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

### **Consulting Agreement with Breaux Castleman**

In June 2003, the Company entered into a consulting agreement with Breaux Castleman, the Chairman of the Company's Board of Directors, for consulting services related to the FDA approval of MelaFind<sup>®</sup>, 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 \$6 in each of the three month periods ending September 30, 2008 and 2007 and \$18 in each of the nine month periods ending September 30, 2008 and 2007. This consulting agreement is terminable by either party by providing thirty days' prior written notice.

#### Consulting Agreement with Marek Elbaum, Ph.D.

Pursuant to a consulting agreement effective as of May 31, 2005, the Company retained Marek Elbaum, Ph.D., the Company's founder and former President and Chief Science and Technology Officer, as the Company's Chief Scientist. In consideration of the services 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 or in the event that Dr. Elbaum's services terminate as a result of his death or disability, the Company agreed to pay Dr. Elbaum a termination fee of \$100. In May of 2007 and effective June 1, 2007, Dr. Elbaum and the Company entered into an amended agreement. Under the terms of the amended agreement, Dr. Elbaum is being paid a monthly fee of \$9 through January 2009.

#### Consulting Agreement with Robert Friedman, M.D.

The Company has retained the services of Robert Friedman, M.D. as a consultant, medical advisor to the Company's Board of Directors, and in connection with the clinical testing of MelaFind<sup>®</sup>. In consideration for these services, Dr. Friedman is being paid at a rate of \$5 per day.

This consulting agreement continues to automatically renew for successive one-year terms unless either party terminates the agreement at least 30 days prior to its expiration. The Company made payments to Dr. Friedman totaling \$33 for the three month period and \$60 for the nine month period ending September 30, 2008, respectively. The Company paid Dr. Friedman \$33 and \$45 for the three and nine month periods ending September 30, 2007.

#### Consulting Agreement with Gerald Wagner, Ph.D.

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. 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<sup>®</sup> in January 2007. The Company recorded a \$140 charge to operations during the nine months ended September 30, 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. The Company recorded a \$162 compensation charge during the first quarter ended March 31, 2006.

In addition, in connection with the start of the Company's pivotal clinical trial at the end of January 2007, Dr. Wagner transitioned out of his role as the Company's Acting Chief Operating Officer and has entered into an amended consulting contract with the Company. Under the terms of the amended contract, Dr. Wagner is paid a monthly retainer of \$2.5 and \$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. The Company paid consulting costs pursuant to this agreement of \$38 in the three month period ended September 30, 2008 compared to \$8 for the same period a year earlier. For the nine month period ending September 30, 2008 and 2007, the Company paid Dr. Wagner \$63 and \$23, respectively.

# 13. SALE AND LICENSING OF DISCONTINUED OPERATIONS

During April 2005, the Company discontinued all operations associated with its DIFOTI<sup>®</sup> product in order to focus its resources and attention on the development and commercialization of MelaFind<sup>®</sup>. 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<sup>®</sup> business were excluded from continuing operations and have been reported as discontinued operations. The assets and liabilities of the business were classified as held for sale. During December 2006, the Company entered into a sale and exclusive licensing agreement with KaVo Dental GmbH ("KaVo"), a leading dental equipment manufacturer, which provides for KaVo to further develop and commercialize DIFOTI<sup>®</sup>. Upon execution of the agreement, KaVo paid the Company \$500. The second \$500 payment was received on July 20, 2007. Beginning in July 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. During the year ended December 31, 2007, the Company recorded \$28 as the balance of the gain on the sale and licensing of its remaining DIFOTI<sup>®</sup> assets, \$781 of the gain had been recorded in the year ended December 31, 2006. Commencing in the third quarter of 2008, royalties are earned on the basis of units sold by KaVo, with the minimum annual royalty being \$20 per year. For the three months ended September 30, 2008, the Company accrued royalty income of \$5.



# 14. SUBSEQUENT EVENTS

On October 10, 2008, the formula-based stock option issued in 2004 to Dr. Gulfo, under the Company's 2003 Plan was cancelled. This option would have been for 743,283 shares of the Company's common stock, assuming PMA approval of MelaFind® had been obtained on September 30, 2008, at an exercise price of \$0.46 a share and Black-Scholes fair value of \$2.74 a share.

On October 10, 2008, Dr. Gulfo was granted stock options for 900,000 shares of the Company's common stock at an exercise price of \$3.75 a share (the closing price on the day of the grant) and Black Scholes fair value of \$2.70 a share; of which (i) 380,000 shares are from shares previously approved for issuance under the 2005 Plan by the Compensation Committee of the Board of Directors and the stockholders of the Company and (ii) 520,000 shares are from shares approved for issuance under the 2005 Plan by the Compensation Committee of the Board of Directors; subject to stockholder approval which is anticipated to be solicited in the Company's 2009 Proxy Statement, but are deemed to have been granted outside the Plan until approved by the stockholders.

The 900,000 shares pursuant to Dr. Gulfo's October 10, 2008 stock option grants vest as follows: (i) 180,000 options vest immediately and are recorded to share-based compensation in the fourth quarter of 2008; (ii) 540,000 options vest upon the Company receiving approval from the FDA of the PMA for MelaFind<sup>®</sup> and will be recorded to share-based compensation upon vesting; and (iii) 180,000 options which vest in four equal annual installments commencing on October 10, 2009 and will be recorded to share-based compensation over the requisite vesting service period. These 900,000 options expire ten years from the date of grant. The cancellation of Dr. Gulfo's 2004 formula-based option and granting of Dr. Gulfo's new stock options are reflected in the following tables updating the stock option tables appearing in Note 8 of this Form 10-Q.

The status of the Company's stock option plans at October 10, 2008 is summarized in the following tables:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,812,084	\$2.96	3.5	
Granted	1,120,039	\$3.60	8.6	
Exercised	(59,070)	\$0.59		
Forfeited or expired	(766,720)	\$0.52	—	—
Outstanding at October 10, 2008	2,106,333	\$4.25	5.8	\$987
Vested and exercisable at October 10, 2008	813,056	\$3.87	4.0	\$790

		Options Outstanding Weighted-		<b>Options Exe</b>	rcisable
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted- Average Exercise Price
\$.01-\$.46	211,753	0.8 years	\$.46	151,753	\$.46
\$.47-\$1.00	105,578	3.2 years	\$1.00	105,578	\$1.00
\$1.01-\$7.75	1,789,002	6.5 years	\$4.89	555,725	\$5.35
\$.01-\$7.75	2,106,333	5.8 years	\$4.25	813,056	\$3.87



# **Table of Contents**

As of October 10, 2008, 448,151 shares remain available for grant under the Company's 2005 Plan. This does not include the 520,000 additional option shares necessary to satisfy the balance of Dr. Gulfo's grant, as previously noted. No shares remain available for grant under the Company's 2003 Plan.

Also in October 2008, Dr. Gulfo exercised 81,753 options that had previously vested, at \$0.46 per share, for a total consideration of \$37,606.38.

ITEM 2.

# ELECTRO-OPTICAL SCIENCES, INC. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This management's discussion and analysis of financial condition and results of operations is intended to provide information to help you better understand and evaluate our financial condition and results of operations. We recommend that you read this section in conjunction with our unaudited condensed financial statements and accompanying notes included under Part I, Item 1 of this Quarterly Report and our financial statements and accompanying notes in our Annual Report on Form 10-K for the year ended December 31, 2007.

This quarterly report on Form 10-Q, including the following 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. Words such as "believe", "anticipate," "expect," "intend," "plan," "will," "may," "should," "estimate," "predict," "potential," "continue," or the negative of such terms or other similar expressions, identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements, and you should not place undue reliance on these statements. Factors that might cause such a difference include those discussed below under the heading "Risk Factors," as well as those discussed elsewhere in this quarterly report on Form 10-Q. 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.

#### 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<sup>®</sup>, 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. We discontinued all operations associated with our DIFOTI<sup>®</sup> product effective as of April 5, 2005 in order to focus our resources and attention on the development and commercialization of MelaFind<sup>®</sup>. On December 11, 2006, we announced that we had signed a sales and exclusive licensing agreement with KaVo Dental GmbH ("KaVo"), a leading dental equipment manufacturer, to further develop and commercialize DIFOTI<sup>®</sup>. In accordance with the terms of the agreement, KaVo paid us an up-front sum and made a second payment to us on July 20, 2007. Beginning in the second half of 2008, KaVo is required to pay us an annual royalty based on the number of systems sold or a set minimum per calendar year following their commercial re-launch of DIFOTI<sup>®</sup>. With the completion of this transaction, we do not have any significant continuing responsibility for the DIFOTI<sup>®</sup> business.

Unless otherwise indicated, the following discussion relates to our continuing operations.

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 September 30, 2008, we had an accumulated deficit of \$56.6 million. We expect to continue to spend significant amounts on the development of MelaFind<sup>®</sup>.

Our revenue for the foreseeable future will depend on the commercialization of MelaFind<sup>®</sup> 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 activities and approvals. At the end of July 2008, we completed the accrual phase of the pivotal trial; follow-up and data analysis is ongoing into the fourth quarter of 2008. 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.

### Liquidity and Capital Resources

Prior to our initial public offering, we financed our operations primarily through the use of working capital from private placements of equity securities and by applying for and obtaining a series of National Institute of Health Small Business Innovative Research grants and similar grants.

In October and November of 2005, we sold a total of 4,262,300 shares of common stock in an initial public offering that resulted in approximately \$17.7 million in net proceeds.

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 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. This transaction closed August 3, 2007.

On June 26, 2008, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed \$40 million. The SEC declared the registration statement effective on July 7, 2008 (file# 333-151935). Management utilized this shelf registration statement to raise additional equity capital by completing a registered direct offering of 2,088,451 shares of the Company's common stock for aggregate gross proceeds of approximately \$11.9 million (\$11 million approximate net proceeds to the Company) at a per share offering price of \$5.68. The offering closed August 8, 2008.

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, activities related to regulatory filings, and manufacturing development efforts. We expense all of our research and development costs as they are incurred.

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 September 30, 2008, total cash, cash equivalents and marketable securities were \$19.6 million. Management anticipates that existing cash balances will allow the Company to fund anticipated levels of operations into 2010. The Company will require additional funds to achieve significant commercialization of MelaFind<sup>®</sup>. However, there can be no assurances that the Company will be able to raise additional capital in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term.

Our cash and cash equivalents at September 30, 2008 are liquid investments in money market funds and deposits with a commercial bank.



## **Cash Flows from Operating Activities**

Net cash used in operations was \$12,069 for the nine months ended September 30, 2008. For the corresponding period in 2007, net cash used in operations was \$8,344. In both periods, cash used in operations was attributable to net losses after an adjustment for non-cash charges related to depreciation/amortization and share-based compensation, and other changes in operating assets and liabilities.

# **Cash Flows from Investing Activities**

For the nine months ended September 30, 2008, net cash provided by our investing activities was \$636 and was principally related to the redemption of marketable securities offset by the purchase of information technology and manufacturing capabilities related equipment in support of MelaFind<sup>®</sup>. For the corresponding period in 2007, net cash used by our investing activities was \$159 that was principally related to the sale of discontinued operations offset by the purchase of marketable securities and purchase of property and equipment.

# **Cash Flows from Financing Activities**

For the nine months ended September 30, 2008, net cash provided by financing activities was \$11,013 and reflects net proceeds from the sale of common stock in a registered direct offering. For the nine months ended June 30, 2007, net cash provided by financing activities was \$10,836 and reflects net proceeds from the sale of common stock in a private placement.

### **Operating Capital and Capital Expenditure Requirements**

We face certain risks and uncertainties, which are present in many emerging medical device companies. At September 30, 2008, we had an accumulated deficit of \$56.6 million. To date, we have not commercialized our principal product, MelaFind<sup>®</sup>. We anticipate that we will continue to incur net losses for the foreseeable future as we continue to develop the MelaFind<sup>®</sup> system, expand our corporate infrastructure, and prepare for the potential commercial launch of MelaFind<sup>®</sup>. We do not expect to generate significant product revenue until we successfully obtain PMA approval for and begin selling MelaFind<sup>®</sup>.

If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of planned product research and 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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup>;
- 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 (in thousands)**

The following table summarizes our outstanding contractual obligations as of September 30, 2008, and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

		Less than			More than
	Total	1 year	1-3 years	4-5 years	5 years
Operating leases	\$539	\$291	\$248	\$ —	\$ —

The indicated operating leases are non-cancelable operating leases for space expiring June 2009 and January 2011. The lease on 5,000 square feet of office and laboratory space expires in June 2009. The lease on 2,800 square feet of office space and the lease for an additional 2,500 square feet of office space adjacent to our existing laboratory location expire in January 2011.

#### **Results of Operations (in thousands)**

Through the first nine months of 2008, the Company continued the development of the MelaFind<sup>®</sup> system, intensified the data accrual activity of the pivotal clinical trial started in 2007, addressed the requirements of the FDA quality system regulation, and initiated the development of processes and equipment to allow for the efficient manufacturing of MelaFind<sup>®</sup> in quantities necessary for commercialization. Even with the completion of the data accrual phase of the pivotal clinical trial at the end of July 2008, as we move toward PMA submission and the commercial launch of MelaFind<sup>®</sup> our overall costs will likely continue to rise due to increases in quality, technical support, and marketing activities.

#### Three Months Ended September 30, 2008 Compared to Three Months Ended September 30, 2007

### **Research and Development Expense**

Research and development expense increased 84% for the three month period ended September 30, 2008 compared to the same period ended September 30, 2007. These cost increases were principally attributable to:

- product development greater use was made of design consultants and subcontractors in 2008 than had been the case in 2007.
- clinical studies costs in 2008 the number of study sites was increased over the number in 2007 when the pivotal clinical trial was just commencing. Additionally, activity in the collection and confirmation of data was intensified both through use of consultants and the hiring of additional in-house clinical personnel.
- quality and regulatory —as we moved closer to PMA submission, we made extensive use of consultants to assist in this process and added in-house personnel to address the requirements of the FDA quality system regulation.
- development activities —we focused on processes and equipment to increase manufacturing capacity as we move toward MelaFind<sup>®</sup> commercialization and product launch. Extensive work was done on developing processes and training of personnel to increase the manufacturing through-put capability of MelaFind<sup>®</sup> manufacturing. In addition, material purchases were made in preparation for the planned increased output.

#### General and Administrative Expense

General and administrative expenses consist primarily of salaries and related expenses of general corporate activities, certain costs associated with our efforts to obtain PMA approval for MelaFind® and development of a commercial infrastructure to market and sell MelaFind®.

General and Administrative expense for the three months ended September 30, 2008 decreased 14% as compared to the same period ended September 30, 2007. This decrease is reflective of marketing consulting activities being slowed during the quarter as the pivotal clinical trial continued through the evaluation period. In 2007, a significantly greater use was being made of marketing consultants during the three month period ended September 30, 2007.

# Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007

### **Research and Development Expense**

Research and development expense increased 77% for the nine month period ended September 30, 2008 compared to the same period ended September 30, 2007, attributable to activities consistent with those described for the three month period above. The percentage increase was less over the full nine month period as the intensified clinical studies and manufacturing process activities began late in the first quarter of 2008.

We continue to work with ASKION, a company that has become an integral member of our MelaFind® development team. ASKION is currently preparing for commercial level production and production of additional MelaFind® systems for other clinical studies of MelaFind®. Our research and development expenses are subject to the risks and uncertainties associated with clinical trials and the FDA regulatory review and approval process. As a result, our research and development expenses could exceed our estimated amounts, possibly materially.

#### General and Administrative Expense

General and administrative expense for the nine months ended September 30, 2008 experienced less than a 1% decrease compared to the same period ended September 30, 2007. Year-to-year increases in salaries, depreciation, and rent have been offset by the decreased utilization of marketing consultants. In the fourth quarter of 2008, proposed new marketing activities relating to the MelaFind® product launch and technical support capabilities for systems to be placed in doctor's offices could increase the level of general and administrative expense.

#### **Interest Income/Expense**

Interest income for the three and nine months ended September 30, 2008 was 62% and 51% lower than the comparable periods in 2007. The decrease is primarily related to the lower interest rates available for investment of our cash balances as well as our average cash balance being \$3.9 and \$3.0 million lower for the three months and nine months ended September 30, 2008, respectively, compared to the same periods a year earlier.

#### **Other Income**

During the three and nine month periods ended September 30, 2008, the Company's other income included \$45 and \$98, respectively, from L'Oreal as an offset to expenses the Company incurred under our joint feasibility program, and \$13 and \$35, respectively, from KaVo for product support of the discontinued dental product line the Company sold to KaVo in 2006. There was \$40 other income earned from L'Oreal under the joint feasibility agreement during the three and nine months ended September 30, 2007.



#### **Deferred Income**

As of September 30, 2008, deferred income of \$2 was billed to KaVo but not yet earned under our product support agreement. There was no deferred income recorded during the nine months ended September 30, 2007.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. 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.

We believe that the following accounting policies and significant judgments and estimates relating to revenue recognition, stock-based compensation charges, and accrued expenses are most critical to aid you in fully understanding and evaluating our reported financial results.

#### **Revenue Recognition**

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

#### **Stock-Based Compensation**

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 Bulletin No. 107. Prior to January 1, 2006, the Company accounted for stock options according to the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value.

The Company adopted the modified prospective transition method provided for under SFAS 123R. Under this transition method, compensation cost associated with stock options in 2007 and 2008 includes: (1) quarterly amortization related to the remaining unamortized 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) quarterly 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.

We have also granted to certain employees stock options that vest with the attainment of milestones not under the Company's control. Upon the attainment of the relevant milestones, there could be a significant compensation charge based on the fair value of such options.

Options or warrants issued to non-employees for services are recorded at fair value and accounted for in accordance with 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* ("EITF 96-18"). For equity instruments that are not immediately vested, compensation costs are measured on the date such instruments vest or a performance milestone is reached, as defined in EITF 96-18. The costs are classified in the accompanying Statement of Operations based on the nature of the service performed.

### **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 are under or over our estimate of the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often subjective determinations. We make these judgments based upon the facts and circumstances known to us in accordance with GAAP. This is done as of each balance sheet date in our financial statements.

#### **Related Party Transactions**

On March 24, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D. which became effective as of April 1, 2006. In connection with his ongoing engagement as a consultant, Dr. Wagner received a stock option grant of 50,000 shares of the Company's common stock which vested upon commencement of the pivotal clinical trial for MelaFind® at the end of January 2007. As Dr. Wagner is a consultant to the Company, we utilize EITF 96-18 to account for this grant. As the pivotal clinical trial began at the end of January 2007, the Company recognized \$140 in compensation expense for this grant.

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. The Company recorded a \$162 compensation charge during the first quarter ended March 31, 2006.

The exercise price for these two stock option grants is the closing price per share of the Company's common stock on the option grant date.

With the start of our pivotal clinical trial, Dr. Wagner has transitioned out of his role as our Acting Chief Operating Officer and has signed an amendment to his 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 \$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 a more detailed description of our related party transactions, see our financial statements and the related notes to our financial statements in Note 12.



#### **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.

#### **Recently Adopted Accounting Pronouncements**

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 the 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 adoption of SFAS No. 159 did not have a material impact on our financial statements.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 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. The adoption of SFAS No. 157 did not have a material impact on our financial statements.

In October 2008, the FASB issued FSP FAS No. 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active." The FSP clarifies the application of SFAS No. 157, "Fair Value Measurements," when the market for a financial asset is not active. The FSP was effective upon issuance, including reporting for prior periods for which financial statements have not been issued. The adoption of the FSP for reporting as of September 30, 2008 did not have a material impact on the Company's financial statements.

# **Recent Accounting Developments**

In March 2008, the FASB issued Statement of Financial Accounting Standards No. 161 "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS 161"). This new standard enhances disclosure requirements for derivative instruments in order to provide users of financial statements with an enhanced understanding of (i) how and why an entity uses derivative instruments, (ii) how derivative instruments and related hedged items are accounted for under Financial Accounting Standards No. 133 "Accounting for Derivative Instruments and Hedging Activities" and its related interpretations, and (iii) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is to be applied prospectively for the first annual reporting period beginning on or after November 15, 2008. We believe that the adoption of SFAS 161 will not have a material impact on our financial statement disclosures since we do not currently have any derivative instruments.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations ("SFAS 141R"). This statement replaces FASB SFAS No. 141 and 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 non-controlling interest in the acquire. 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 believe the adoption of this pronouncement will not have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, Non-controlling Interests in Consolidated Financial Statements—an amendment of ARB No. 51. This statement amends ARB 51 to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling 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 believe the adoption of this pronouncement will not have a material impact on the our financial statements.

In April 2008, the FASB issued FSP FAS No. 142-3, "Determination of the Useful Life of Intangible Assets." The FSP amends the factors an entity should consider in developing renewal or extension assumptions used in determining the useful life of recognized intangible assets under SFAS No. 142, "Goodwill and Other Intangible Assets." The FSP must be applied prospectively to intangible assets acquired after the effective date. The Company will apply the guidance of the FSP to intangible assets acquired after January 1, 2009.

# ITEM 3.

#### Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is confined to our cash, cash equivalents, and short-term investments. We invest in high-quality financial instruments, primarily money market funds, federal agency notes, and US Treasury obligations, with the average effective duration of the portfolio within one year which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments. The Company is exposed to credit risks in the event of default by the financial institutions or issuers of investments in excess of FDIC insured limits. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any institution,

### ITEM 4.

#### **Controls and Procedures**

#### Evaluation of disclosure controls and procedures

Based on their evaluation as of September 30, 2008, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

### Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2008 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 4T. Controls and Procedures**

Not applicable.

# PART II. OTHER INFORMATION

### **Item 1. 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.

#### Item 1A. Risk Factors

Our business and operations entail a variety of serious risks and uncertainties, including those described in Item 1A of our Form 10-K for the year ended December 31, 2007. In addition, the following risk factors have changed during the nine months ended September 30, 2008:

### 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<sup>®</sup>. MelaFind<sup>®</sup> 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<sup>®</sup>, or the approved indication may be narrower than we seek;
- MelaFind<sup>®</sup> 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<sup>®</sup> and we will not have adequate financial or other resources to achieve significant commercialization of MelaFind<sup>®</sup>;
- 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<sup>®</sup> before the middle of 2009. If we are unable to develop, obtain regulatory approval for or successfully commercialize MelaFind<sup>®</sup>, we will be unable to generate revenue.

#### Risk of delay in product development.

We could encounter delays in our pivotal clinical 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 is required to be completed before the classifier is utilized as described above. Accordingly, the classifier must be ready for final training when the data from the pivotal trial become available. 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 clinical 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<sup>®</sup>.

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

We do not have the necessary regulatory approvals to market MelaFind<sup>®</sup> 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<sup>®</sup>, once approved, in the US. The regulatory approval process for MelaFind<sup>®</sup> in the US involves, among other things, successfully completing clinical trials and obtaining pre-market approval (PMA) from the FDA. We commenced the PMA application process for MelaFind<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> to assist in determining the appropriateness of biopsies of suspicious pigmented skin lesions. Before submitting a PMA application, we must successfully complete a pivotal clinical trial to demonstrate that MelaFind<sup>®</sup> 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 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.

The accrual phase of the MelaFind<sup>®</sup> pivotal trial concluded at the end of July 2008. Follow-up and data analysis is ongoing and will continue through the fourth quarter of 2008.

#### 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<sup>®</sup>. Our net loss for the three and nine months ended September 30, 2008 was approximately \$4.2 million and \$13.4 million, respectively, and as of September 30, 2008, we had an accumulated deficit of approximately \$56.6 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind<sup>®</sup>. If we receive PMA approval for MelaFind<sup>®</sup> from the FDA, we expect to incur significant sales and marketing expenses, which will require additional funding, and manufacturing expenses. Additionally, our general and administrative expenses have also increased due to the additional operational and regulatory responsibilities applicable to public companies. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

As of September 30, 2008, we had \$18.8 million in cash and cash equivalents and \$0.8 million in marketable securities. Our operations have consumed substantial amounts of cash for each of the last eight years. The Company will require additional funds to achieve significant commercialization of MelaFind<sup>®</sup>. However, there can be no assurances that the Company will be able to raise additional capital in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term.

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<sup>®</sup> 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<sup>®</sup>;
- 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.

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.

# MelaFind<sup>®</sup> 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<sup>®</sup> 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 long-term commercial success of MelaFind<sup>®</sup> in both domestic and international markets will significantly depend on whether third-party coverage and reimbursement are available for services involving MelaFind<sup>®</sup>. 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<sup>®</sup>. 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<sup>®</sup> 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 statutory provisions intended to facilitate coverage determinations for new technologies, but it is unclear how these 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 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<sup>®</sup>, it may undermine the commercial viability of MelaFind<sup>®</sup>.

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.

#### Our stock price is likely to be volatile, meaning purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. Between October 28, 2005 (the date of our initial public offering) and September 30, 2008, our stock price has ranged from \$3.29 to \$9.99 per share. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:

- results of our research and development efforts and our clinical trials;
- the timing of regulatory approval for our products;
- failure of any of our products, if approved, to achieve commercial success;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the US and foreign countries;
- ability to manufacture our products to commercial standards;
- developments concerning our clinical collaborators, suppliers or marketing partners;
- changes in financial estimates or recommendations by securities analysts;
- public concern over our products;
- developments or disputes concerning patents or other intellectual property rights;
- product liability claims and litigation against us or our competitors;

- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of and third-party reimbursement in the 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, if brought, 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 September 30, 2008, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates in the aggregate, beneficially owned approximately 36% 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.

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

We have not yet completed the development and testing of MelaFind<sup>®</sup>, and as a result have no experience in manufacturing MelaFind<sup>®</sup> for commercial distribution. We currently have limited resources, facilities and experience to commercially manufacture MelaFind<sup>®</sup>. In order to produce MelaFind<sup>®</sup> 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 production to contract manufacturers. Any difficulties in the ability of third-party manufacturers to supply devices of the quality, at the times, and in the quantities we need, could have a material adverse effect on our business, financial condition, and results of operations. Similarly, when we enter into contracts for the third-party manufacture of our devices, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Manufacturers often encounter difficulties in scaling up production of new products, including problems involving product yields, controlling and anticipating product costs, quality control and assurance, component supply, and shortages of qualified personnel. We cannot assure you that the third-party contract manufacturers with whom we have developed or are developing relationships will have or sustain the ability to produce the quantities of MelaFind® needed for development or commercial sales, or will be willing to do so at prices that allow MelaFind® to compete successfully in the market.

Assuming that MelaFind<sup>®</sup> 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<sup>®</sup> receives regulatory approval and we then need to make manufacturing changes, we may need to obtain additional approval for these changes.

MelaFind<sup>®</sup> 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.

# We will not be able to sell MelaFind<sup>®</sup> 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 Regulations.

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 middle of 2009. 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 Regulations ("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<sup>®</sup> 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<sup>®</sup>, 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." A second follow-up inspection was conducted in May 2008; no deficiencies were cited by the FDA field inspector.

Our director of quality assurance and regulatory affairs continues to work with several regulatory consultants to address the inspectional findings, particularly as they relate to current MelaFind<sup>®</sup> design development and ultimately MelaFind<sup>®</sup> 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<sup>®</sup>, or in our efforts to address any MelaFind<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup>;
- 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.

# Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

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. This transaction closed on August 3, 2007.

The proceeds from this financing are being used for general corporate purposes including research and development activities.

### Item 3. Defaults Upon Senior Securities.

Not applicable.

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

Not applicable.

# Item 5. Other Information

- (a) Not applicable
- (b) Not applicable

# **Table of Contents**

# Item 6. Exhibits

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)
	34

Table	of	Contents

Exhibit Number	Exhibit Title
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)
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 the 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.(1)
10.31*	Employment Offer Letter, dated February 11, 2008, between the Registrant and Tina Cheng-Avery.(14)
10.32*	Separation Agreement dated May 1, 2008, between the Registrant and Jon I. Klippel. (15)
10.33	Form of Subscription Agreement between the Registrant and certain investors.(16)

Tabl	e of	Content	s

Exhibit	

#### Number

#### Exhibit Title

- 31.1# Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 31.2# Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 32.1# Certification 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.

(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.

# Filed herewith.

<sup>\*</sup> Indicates management compensatory plan, contract or arrangement

<sup>(1)</sup> 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.

<sup>(2)</sup> 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.

<sup>(4)</sup> Incorporated by reference to the Registrant's Current Report on Form 8-K filed on January 31, 2006.

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

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

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

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

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

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

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

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

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

<sup>(14)</sup> Incorporated by reference to the Registrant's Current Report on Form 8-K filed on February 12, 2008.

<sup>(15)</sup> Incorporated by reference to the Registrant's Current Report on Form 8-K filed on May 1, 2008.

<sup>(16)</sup> Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 31, 2008.

<sup>36</sup> 

# SIGNATURES

Pursuant to the requirements of the Securities 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/ Richard I. Steinhart Richard I. Steinhart Vice President and Chief Financial Officer (Principal Accounting and Financial Officer)

Date: November 6, 2008

# EXHIBIT INDEX

# Exhibit No.

#### Description

- 31.1 Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 31.2 Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

# CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(A) or RULE 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Joseph V. Gulfo, certify that:

- 1. I have reviewed this report on Form 10-Q 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; and
  - 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.

Date: November 6, 2008

/s/ Joseph V. Gulfo, M.D.

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

# CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13A-14(A) or RULE 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Richard I. Steinhart, certify that:

- 1. I have reviewed this report on Form 10-Q 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; and
  - 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.

Date: November 6, 2008

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

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

Each of the undersigned officers of Electro-Optical Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the period ended September 30, 2008 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo

Joseph V. Gulfo President and Chief Executive Officer (Principal Executive Officer) November 6, 2008

/s/ Richard I. Steinhart Richard I. Steinhart Vice President & Chief Financial Officer (Principal Accounting and Financial Officer) November 6, 2008

<sup>\*</sup> 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-Q 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.