#### 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 $\checkmark$ **ACT OF 1934**

For the quarterly period ended September 30, 2006

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)

### **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.

#### Yes 🗹 No o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer  $\square$ 

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 13, 2006 13,276,986 shares of the Registrant's Common stock were outstanding.

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

> 10533 (Zip Code)

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#### ELECTRO-OPTICAL SCIENCES, INC. CONDENSED BALANCE SHEETS

	September 30, 2006 (unaudited)	December 31, 2005 *
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 9,598,868	\$ 18,505,030
Marketable securities	998,170	
Prepaid expenses and other current assets	97,557	210,940
Assets held for sale	156,677	156,677
Total Current Assets	10,851,272	18,872,647
Property and equipment, net	552,065	175,369
Patents and trademarks, net	100,751	84,052
Other assets	39,758	33,612
Total Assets	\$ 11,543,846	\$ 19,165,680

#### LIABILITIES AND STOCKHOLDERS' EQUITY

#### **Current Liabilities:**

Accounts payable (includes related parties of \$24,500 as of September 30, 2006 and \$11,263 as of December 31,		
2005)	\$ 384,140	
Accrued expenses (includes related parties of \$15,000 as of December 31, 2005)	291,845	

Other current liabilities	13,703	16,828
Total Current Liabilities	689,688	916,342

\$

329,462 570,052

#### COMMITMENTS AND CONTINGENCIES

#### **Stockholders' Equity**

Common stock — \$.001 par value; authorized 30,000,000 shares; issued and outstanding 10,952,602 shares at		
September 30, 2006 and 10,837,833 shares at December 31, 2005	10,953	10,838
Additional paid-in capital	39,718,744	38,934,420
Deferred compensation		(62,610)
Other comprehensive loss	(401)	
Accumulated deficit	(28,875,138)	(20,633,310)
Stockholders' Equity	10,854,158	18,249,338
Total Liabilities and Stockholders' Equity	\$ 11,543,846	\$ 19,165,680

\* Derived from the audited balance sheet as of December 31, 2005

See accompanying notes to the financial statements

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

		Three months ended September 30,		Nine months ended September 30,		
	2006	2005	2006	2005		
Operating expenses:						
Research and development	\$ 1,647,892	\$ 876,193	\$ 5,653,768	\$ 2,422,017		
General and administrative	928,861	491,976	3,093,144	1,487,907		
Operating loss from continuing operations	(2,576,753)	(1,368,169)	(8,746,912)	(3,909,924)		
Interest income (expense)	151,543	(2,574)	505,084	60,195		
Loss from continuing operations	(2,425,210)	(1,370,743)	(8,241,828)	(3,849,729)		
Loss from discontinued operations		(71,966)	<u> </u>	(402,077)		
Net loss	(2,425,210)	(1,442,709)	(8,241,828)	(4,251,806)		
Less:						
Preferred stock deemed dividends	—	359,531	—	1,078,595		
Preferred stock accretion	_	323,247	_	969,743		
Net Loss Attributable to Common Stockholders	\$ (2,425,210) \$ (2,12		\$ (8,241,828)	\$(6,300,144)		
Net loss per common share, basic and diluted:						
Continuing operations	\$ (0.22)	\$ (1.10)	\$ (0.76)	\$ (3.22)		
Discontinued operations	_	(0.04)	_	(0.22)		
Basic and diluted net loss per common share	\$ (0.22)	\$ (1.14)	\$ (0.76)	\$ (3.44)		
Basic and diluted weighted average number of Common shares						
outstanding	10,938,732	1,869,011	10,886,985	1,829,726		

See accompanying notes to the financial statements

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

	Nine Months Ended Septeml		
	2006	2005	
Cash flows from operating activities:	(unaudited)	(unaudited)	
Loss from continuing operations	\$ (8,241,828)	\$(3,849,729)	
Loss from discontinued operations		(402,077)	
Net loss	(8,241,828)	(4,251,806)	
Adjustments to reconcile net loss to net cash used in operating activities:	(0,=11,0=0)	(1,201,000)	
Allowance for doubtful accounts	_	(1,000)	
Depreciation and amortization	88,025	36,480	
Noncash compensation and amortization of deferred compensation	778,119	129,195	
Amortization of discount on marketable securities	_	(33,502)	
Changes in operating assets and liabilities:			
Decrease in receivables	—	8,128	
Increase in inventories	_	(16,122)	
Decrease in prepaid expenses and other current assets	113,383	23,654	
Increase in other assets	(6,146)		
(Decrease)/ increase in accounts payable and accrued expenses	(223,529)	38,505	
Decrease in deferred revenues	_	(106,335)	
Decrease in other current liabilities	(3,125)	(6,408)	
Net cash used in operating activities	(7,495,101)	(4,179,211)	
Cash flows from investing activities:			
Patent costs	(30,637)	(2,822)	
Purchases of property and equipment	(450,783)	(115,830)	
Net (purchase) redemption of marketable securities	(998,571)	6,628,253	
Net cash (used in) provided by investing activities	(1,479,991)	6,509,601	
Cash flows from financing activities:		<u> </u>	
Payment for stock subscription receivable	_	34,500	
Proceeds from exercise of stock options	68,930		
Deferred registration costs	_	(1,135,122)	
Proceeds from sale of common stock		7,300	
Net cash provided by (used in) financing activities	68,930	(1,093,322)	
Net (decrease) increase in cash and cash equivalents	(8,906,162)	1,237,068	
Cash and cash equivalents at beginning of period	18,505,030	108,705	
Cash and cash equivalents at end of period	\$ 9,598,868	\$ 1,345,773	
	\$ 9,590,000	\$ 1,040,770	
Supplemental Schedule of Noncash Financing Activities:			
Preferred stock accretion		\$ 969,743	
Reclassification of inventories and patents to assets held for sale		\$ 156,677	
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See accompanying notes to 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 (the "Company"), is focused on the design and development of MelaFind<sup>®</sup>, a non-invasive, point-ofcare instrument for assisting in the early diagnosis of melanoma. The Company has entered into a protocol agreement with the Food and Drug Administration ("FDA") which is an agreement for the conduct of the pivotal trial and to establish the safety and effectiveness of the MelaFind<sup>®</sup> device. On October 12, 2006, we announced that the FDA had informed the Company that when submitted, the MelaFind<sup>®</sup> 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<sup>®</sup> FDA approval process, the Company can give no assurances that this will be the case. Upon obtaining premarket approval from the FDA, the Company plans to launch MelaFind<sup>®</sup> in the United States.

To date the Company has not generated any revenues from MelaFind<sup>®</sup>. All of the Company's historical revenues have come 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>. The Company is currently seeking a buyer for the DIFOTI<sup>®</sup> assets, and does not expect to have any significant continuing responsibility for the DIFOTI<sup>®</sup> business after the sale of the DIFOTI<sup>®</sup> assets.

As previously noted, the Company has not generated any revenues from its principal business activity. As a result, the Company has incurred significant losses from operations, and it is anticipated that it will continue to generate significant losses from operations for the foreseeable future. Operations to date have been funded with proceeds from public and private equity placements, research grants, and income earned from investments. On October 31, 2006, and as more fully described in Note 13, the Company entered into securities purchase agreements and a registration rights agreement for the private placement of 2,312,384 common shares of the Company's common stock and warrants to purchase up to 346,857 shares of the Company's common stock. Gross proceeds were approximately \$13.2 million, and net proceeds totaled approximately \$12.5 million. The proceeds from this financing along with the proceeds from our 2005 IPO, will allow the Company to meet its anticipated cash needs for working capital and capital expenditures through mid 2008.

The unaudited 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 for reporting on Form 10-Q. The information and note disclosures normally included in complete financial statements prepared in accordance with accounting principles generally accepted 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, 2005.

The Company 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 statements have been included and are of a normal and recurring nature.

#### 2. MARKETABLE SECURITIES

The Company's marketable securities are debt securities primarily consisting of government obligations and corporate debt securities with a weighted average maturity not in excess of six months. The Company's marketable securities are classified 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 income (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, 2006, marketable securities consisted of obligations of US government agencies on which the Company has recorded an unrealized loss of \$0.4.

The Company evaluates declines in fair value of our 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 for the period 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 other comprehensive loss in stockholders' equity on the Company's balance sheet. For the nine months ended September 30, 2006, comprehensive loss amounted to \$8,242.

#### 4. USE OF ESTIMATES

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

#### 5. RECENT ACCOUNTING DEVELOPMENTS

In February 2006, the Financial Accounting Standards Board (FASB) issued SFAS Statement No. 155, "Accounting for Certain Hybrid Financial Instrumentsan amendment of Statements No. 133 and 140" (FAS 155). FAS 155 is effective for fiscal years that begin on or after October 1, 2006 and would permit companies the option to use a fair value measurement for certain hybrid financial instruments that contain an embedded derivative that would otherwise require bifurcation under under FAS 133. The Company does not expect the adoption of FAS 155 to have a material impact on its financial statements.

In July 2006, FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109" (FIN 48), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company does not expect the adoption of FIN 48 to have a material impact on its financial reporting, and we are currently evaluating the impact, if any, the adoption of FIN 48 will have on its disclosure requirements.

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

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, and consequently, has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options recognized in the three month and nine month periods ended September 30, 2006 includes: (1) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006 over the requisite service period based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*; and (2) amortization related to all stock option awards granted on or subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. A compensation charge is recorded when it is probable that performance 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.

As a result of the adoption of SFAS 123R, incremental compensation expense for the three and nine month periods ended September 30, 2006 amounted to \$195 and \$554, respectively. At September 30, 2006 total unrecognized compensation cost amounted to approximately \$1,741, representing 832,082 unvested options.

For stock options granted prior to the adoption of SFAS 123R, if compensation expense for the Company's various stock option plans had been determined based upon estimated fair values at the grant dates in accordance with SFAS No. 123, the Company's pro forma net loss attributable to common stockholders and pro forma basic and diluted net loss per common share would have been as follows:

	Septen	Months Ended <u>nber 30, 2005</u> n thousands except	Nine Months Ended <u>September 30, 2005</u> t per share amounts)	
Net loss attributable to common stockholders, as reported	\$	(2,125)	\$	(6,300)
Add: Stock-based employee compensation expense included in reported net loss, net of related tax effect		8		95
Deduct: Stock-based employee compensation expense determined under fair-value-based method, net of				
related tax effect		(9)		(99)
Pro forma net loss attributable to common stockholders	\$	(2,126)	\$	(6,304)
Basic and diluted net loss per common share:				
As reported	\$	(1.14)	\$	(3.44)
Pro forma	\$	(1.14)	\$	(3.45)

#### 6. NET LOSS PER COMMON SHARE

Net loss per share is presented in accordance with the provisions of SFAS No. 128, *Earnings Per Share* (EPS). Basic EPS excludes dilution for potentially dilutive securities and is computed by dividing loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to dilutive options, warrants and other potential common shares outstanding during the period. Diluted net loss per common share since all potentially dilutive securities are anti-dilutive for each of the periods presented. Potential common stock equivalents excluded consist of stock options, warrants and redeemable convertible preferred stock which are summarized as follows:

	Septe	ember 30,
	2006	2005
Common stock options	1,571,934	919,035
Warrants	285,835	2,729,916
Redeemable convertible preferred stock	—	3,398,105
Total	1,857,769	7,047,056

#### 7. STOCK-BASED COMPENSATION AND DEFERRED COMPENSATION

The Company has three stock-based compensation plans, (the "Plans") which allow the Board of Directors to grant incentives to employees, directors and collaborating scientists in the form of incentive stock options, nonqualified stock options and restricted stock awards.

The compensation expense recognized in the Statement of Operations in the third quarter of 2006 for stock options and restricted stock awards amounted to \$204, and for the nine months ended September 30, 2006 compensation expense amounted to \$778. Cash received from options exercised under all share-based payment arrangements for the three and nine months ended September 30, 2006 was \$31 and \$69, respectively.

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

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

	For the Nine Months Ended September 30, 2006
Expected life	5 years
Expected volatility	60%
Risk-free interest rate	5.04%

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 based on implied volatility from other publicly-traded options and other factors. The risk-free interest rate is based on the continuous rates provided by the U.S. Treasury with a term equal to the expected life of the option.

The status of the Company's stock option plans at September 30, 2006 is summarized as follows:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term in Years	I	gregate ntrinsic Value
Outstanding at December 31, 2005	1,115,415	\$ 0.95	4.4	\$	4,935
Granted	598,958	6.40	4.6	\$	(655)
Exercised	(109,835)	.63	N/A	\$	573
Forfeited or expired	(32,604)	6.75	N/A		(35)
Outstanding at September 30, 2006	1,571,934	2.93	4.4	\$	3,764
Vested and exercisable at September 30, 2006	532,524	1.79	4.5	\$	1,873

During the third quarter of 2006 the weighted average fair value of each option granted, estimated as of the grant date using the Black-Scholes option valuation model, was \$3.45 per share, and for the nine months ended September 30, 2006 the weighted average was \$3.76 per share. The total intrinsic value of options exercised during the three and nine months ended September 30, 2006 was \$345 and \$573, respectively.

The requisite service periods for options granted in the first three and nine months of 2006 for employees and consultants were five years.

Stock awards under the Company's current plan are granted at prices which are equal to 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 under this plan expire five years from the date of grant. Since the Company has adopted the 2005 Plan, awards are not issued under the Company's previous stock option plans; however, additional shares are reserved for issuance pursuant to the 2003 Plan in connection with a formula-based option granted to Dr. Gulfo, as described below. As of September 30, 2006, of the total 1,571,934 options outstanding (including 50,000 options awarded to a consultant) 1,039,410 have not vested. Of this total nonvested amount, 921,162 will vest upon the attainment of certain milestones and the balance will vest over the requisite service period. As of September 30, 2006, there was \$1,883 of total unrecognized compensation cost related to nonvested options (including \$142 of deferred compensation). As of September 30, 2006 there were 683,609 shares available for future grants under the Company's 2005 plan.

In connection with the employment agreement with the President and Chief Executive Officer (Dr. Gulfo), three separate grants of common stock options were made to Dr. Gulfo. The first two stock option grants for a total of 81,753 shares of the Company's common stock have fully vested. The number of shares of the Company's common stock subject to the third stock option can only be calculated at the time of PMA approval of MelaFind<sup>®</sup>. The number of shares under this option is equal to that number of shares of the Company's common stock equal to four percent of the Company's fully diluted capital stock at the time of PMA approval of MelaFind<sup>®</sup> minus the 81,753 options granted to Dr. Gulfo under the employment agreement. At September 30, 2006, total unvested options outstanding for Dr. Gulfo amounted to 430,662.

On March 24, 2006, the Company issued to its Acting Chief Operating Officer and a member of the Board, Dr. Gerald Wagner, a stock option grant of 49,500 shares of the Company's common stock which vested immediately. The exercise price for this stock option grant was the closing price per share of the Company's common stock on the option grant date which was \$5.87 per share. The fair value of this option grant was determined using the Black-Scholes option valuation model on the date of the grant. Compensation expense of \$162 was charged to operations during the first quarter 2006.

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

On May 29, 2006 the Company entered into an agreement with Christiano S. Butler to serve as the Company's Vice-President of Technical Support. In accordance with that agreement, Mr. Butler received a five year option under the Company's 2005 Plan to purchase up to 40,000 shares of common stock at \$7.60.

At the Company's May 22, 2006 Board of Directors meeting, the Board approved management's recommendation to award stock options to a group of 27 employees. A total of 315,500 shares (excluding Mr. Steinhart's and Mr. Butler's options) were awarded to Company employees under the Company's 2005 Plan.

#### **Deferred Compensation**

Options or warrants issued to non-employees for services are recorded at fair value and accounted for in accordance with Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.* For equity instruments that are not immediately vested, compensation cost is measured on the date such instruments vest or a performance commitment is reached, as defined in EITF 96-18. Prior to the effective date of SFAS 123R, the Company recorded deferred compensation during the quarter the grant was issued for the entire option value based on the Black Scholes valuation model. Subsequently, the deferred compensation was adjusted each quarter until vesting occurred and the charge was taken. Deferred compensation attributable to non-vested options or restricted stock was reflected as a reduction of stockholders' equity. In accordance with SFAS 123R, deferred compensation is no longer allowed to be recorded for the unvested portion of options and warrants, and accordingly, during 2006, the Company eliminated the deferred compensation balance with a corresponding reduction in additional paid-in-capital. The costs are classified in the accompanying Statement of Operations based on the nature of the service performed.

On March 24, 2006, the Company issued to Dr. Wagner, in connection with his on-going engagement as a consultant, a stock option grant of 50,000 shares of the Company's common stock which fully vests immediately upon commencement of the pivotal trial for MelaFind® and a stock option grant of 49,500 shares of the Company's common stock which was fully vested on the grant date. The exercise price for this stock option grant is the closing price per share of the Company's common stock on the option grant date which was \$5.87 per share. The fair value of this option grant is determined using the Black-Scholes options valuation model at each reporting date until vesting has occurred. As of September 30, 2006, total unrecognized compensation for this grant amounted to \$142.

In December 2005, the Company issued a restricted common stock award of 11,488 shares to an employee at the closing market price of the Company's stock on the date of grant, and compensation expense in the amount of \$63 for this award was recognized on a straight line basis over the nontransferable period. For the three and nine month periods ended September 30, 2006, \$9 and \$63 respectively was charged to compensation expense. As of September 30, 2006 this award was fully amortized.

#### 8. COMMITMENTS AND CONTINGENCIES

In connection with the planned start of clinical trials, the Company has committed to several clinical sites a total amount of approximately \$173 in contracts that do not exceed one year. These contracts are cancelable with 30 days prior notice.

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

4Q 2006		2007	2008	2009	2010
\$	61	\$ 249	\$ 253	\$ 188	\$ 105

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, for the MelaFind<sup>®</sup> units which will be used in the Company's pivotal clinical trials. We expect this work to take place throughout the balance of 2006 and into 2007.

On March 24, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D., Acting Chief Operating Officer and a member of the Company's Board of Directors. The effective date of this amended and restated agreement is April 1, 2006. Under this amended consulting agreement, the Company agreed to pay Dr. Wagner an annual amount of \$180 payable monthly over the term of the agreement. The agreement will end at the option of Dr. Wagner or the Company, at any time by providing thirty days prior written notice or immediately upon the mutual agreement of the Company and Dr. Wagner (See Note 7).

In January 2006, the Company entered into an agreement with ASKION GmbH ("ASKION") to produce and test commercial grade MelaFind<sup>®</sup> hand-held imaging device systems. Under the agreement, ASKION is to produce up to forty MelaFind<sup>®</sup> imaging devices for the Company to be utilized in the Company's pivotal trial which will be conducted at up to twenty clinical study sites in the United States. The Company is required to make payments to ASKION upon delivery of the MelaFind<sup>®</sup> systems.

This contract commenced in February 2006 and is expected to be completed later this year. Payments to ASKION during 2006 have totaled approximately \$1,828 of which approximately \$1,300 was paid in accordance with this agreement. In addition, pursuant to the agreement, the Company has instituted additional test procedures at ASKION to ensure proper operation of the MelaFind<sup>®</sup> systems. These test procedures will require additional funding and the payments for this testing will take place over the next several months.

During January 2004, the Company entered into an employment agreement with its President and Chief Executive Officer through December 31, 2005, which provided for a base salary of \$175, stock options and performance bonuses. The agreement provided for automatic one year renewal terms and renewed automatically for 2006. Effective May 31, 2006 the base salary was increased to \$235, and he received a bonus in the amount of \$50.

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

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

#### 9. INITIAL PUBLIC OFFERING

On October 28, 2005, the Company completed an initial public offering. The Company issued 4,000,000 shares of common stock on October 28, 2005 and 262,300 shares of common stock on November 15, 2005, both issuances at \$5.00 per share. After deducting underwriting discounts and expenses and offering-related expenses, the initial public offering resulted in net proceeds to the Company of approximately \$17,687. In connection with the initial public offering, all of the outstanding shares of the Company's redeemable convertible preferred stock were automatically converted into 3,398,105 shares of the Company's common stock, and all related deemed but unpaid dividends on the redeemable convertible preferred stock were forfeited.

#### **10. WARRANTS**

During 2005, the Company issued 1,305,321 shares of common stock in exchange for 2,610,643 outstanding warrants (a conversion ratio of one share of common stock for two warrants). The Company recorded this transaction as an exchange of equity instruments at fair value which had no net effect on stockholders' equity. The fair value of the warrants was determined using the Black-Scholes method and assumed the following: common stock value of \$10.00 per share, remaining warrant life of 6.25 years, risk-free interest rate of 3.2%, and an expected volatility of 60%.

The warrants outstanding at September 30, 2006 consist of a 5 year warrant to purchase 75,000 shares of common stock at an exercise price of \$7.00 per share issued to one of the Company's consultants in 2004, and 7 year warrants to purchase an aggregate of 60,835 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.

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

#### 11. RELATED PARTY CONSULTING AGREEMENTS (see Note 7)

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 and \$23, respectively, for the three and nine month period ending September 30, 2006. 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 has agreed to pay Dr. Elbaum a monthly fee of \$15. The term of this agreement extends for a period of two years and is automatically renewable for an additional one year period. In the event of a non-renewal or in the event that Dr. Elbaum's services terminate as a result of his death or disability, we will pay Dr. Elbaum a termination fee of \$100.

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

Effective as of June 1, 2005, the Company retained the services of Robert Friedman, M.D., for an initial term of one year as a consultant, medical advisor to our Board of Directors, and in connection with the clinical testing of MelaFind<sup>®</sup>. In consideration for these services, Dr. Friedman will be paid at a rate of \$5 per day. This consulting agreement automatically renewed effective June 1, 2006 for an additional one-year term and is automatically renewable for successive one-year terms unless either party terminates the agreement at least 30 days prior to the expiration of the agreement. The Company made payments to Dr. Friedman totaling \$5 and \$27, respectively, for the three and nine month period ending September 30, 2006.

#### 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., Acting Chief Operating Officer and a member of the Company's Board of Directors. The effective date of this amended and restated agreement is April 1, 2006. Under this amended consulting agreement, the Company agreed to pay Dr. Wagner the annual amount of \$180 payable monthly over the term of the agreement. The agreement will end at the option of Dr. Wagner or the Company, at any time by providing thirty days prior written notice or immediately upon the mutual agreement of the Company and Dr. Wagner. In addition, in connection with his ongoing engagement as a consultant, Dr. Wagner received a stock option grant of 50,000 shares of the Company's common stock which vests in full immediately upon commencement of the pivotal trial for MelaFind®. Also, on March 24, 2006, Dr. Wagner received another stock option grant of 49,500 shares of the Company's common stock which vested immediately. (See Note 7.)

#### 12. DISCONTINUED OPERATIONS AND ASSETS HELD FOR SALE

During the period March 9 through March 21, 2005, the Company was inspected by the FDA in connection with its DIFOTI® product, a non-invasive imaging device for the detection of dental cavities. On March 21, 2005, the Company was cited for failure to comply fully with FDA Quality System Regulation, or QSR, mandated procedures. These inspectional findings were discussed in a subsequent meeting with the FDA on April 28, 2005. The Company is in the process of addressing the deficiencies noted in accordance with the agreement reached with the FDA. On May 18, 2006, the FDA visited the Company's facility for a follow-up inspection. No non-conformities or negative observations were reported to the Company.

The Company decided to discontinue all operations associated with its DIFOTI<sup>®</sup> product effective as of April 5, 2005, in order to focus its resources and attention on the development and commercialization of MelaFind<sup>®</sup>. The Company is currently seeking an acquirer for the DIFOTI<sup>®</sup> assets and does not expect to have any significant continuing responsibility for the DIFOTI<sup>®</sup> business after its disposition. Losses attributable to DIFOTI<sup>®</sup> operations discontinuance in April 2005 amounted to \$72 for the quarter ended September 30, 2005 and \$402 for the nine months then ended.

SFAS No. 144 requires that long-lived assets to be disposed by sale be measured at the lower of carrying amount or fair value less cost to sell. SFAS No. 144 also broadened the reporting of discontinued operations to include all components of an entity with operations that will be eliminated from ongoing operations of the entity in a disposal transaction. At September 30, 2006, assets held for sale consisted of DIFOTI<sup>®</sup> related inventories and patents.

#### **13. SUBSEQUENT EVENTS**

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. The private placement closed on November 3, 2006. Pursuant to the securities purchase agreements, for a purchase price of \$5.70 each investor received one share of the Company's common stock and a warrant to purchase 0.15 of a share of common stock. The warrants are five-year warrants with an exercise price of \$6.70 per share. 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 agreement, the Company has agreed to cause a resale registration statement covering the shares, including the shares issuable upon exercise of the warrants, to be filed within 30 days after closing.

The approximately \$12.5 million in net proceeds from the closing will be used for general corporate purposes. The proceeds from this financing along with the proceeds from the 2005 IPO, will allow the Company to meet its anticipated cash needs for working capital and capital expenditures through mid 2008.

William R. Bronner resigned as our Secretary and Vice President, Legal Counsel and Compliance, effective as of November 9, 2006. Our Board of Directors appointed Richard Steinhart, the Company's Vice President of Finance and Chief Financial Officer as Secretary to replace Mr. Bronner as Secretary. In connection with Mr. Bronner's resignation, we entered into a letter agreement dated November 9, 2006 regarding the terms of his resignation (the "Resignation Agreement").

Pursuant to the Resignation Agreement, Mr. Bronner will (i) continue as an employee through November 30, 2006 at his current salary, (ii) be engaged as a consultant for a period of thirteen months, commencing December 1, 2006, at an annual rate of \$50,000 and (iii) receive a lump sum payment of \$50,000 during the first week of January, 2007 as consideration for all vacation and other personal time and compliance with the terms of the Resignation Agreement. Mr. Bronner is entitled to exercise his stock options to purchase up to 78,535 shares of our common stock previously granted to him pursuant to our stock incentive plans for a period of ninety days following November 30, 2006. All such stock options that are subject to vesting will become fully vested as of November 30, 2006. The Resignation Agreement contains a general release from Mr. Bronner, the effectiveness of which is subject to statutory review and revocation periods. In addition, the Resignation Agreement contains certain mutual non-disparagement covenants.

#### 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 Financial Statements and Notes to Financial Statements and with our Annual Report on Form 10-K for the year ended December 31, 2005.

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 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; however, the financial results for all periods discussed below account for the revenues and the related expenses associated with our DIFOTI<sup>®</sup> product, a non-invasive imaging device for the detection of dental cavities, as a discontinued operation. We decided to discontinue all operations associated with our DIFOTI<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>. We are currently seeking an acquirer for the DIFOTI<sup>®</sup> assets, and we do not expect to have any significant continuing responsibility for the DIFOTI<sup>®</sup> business after its disposition. Unless otherwise indicated, the following discussion relates to our continuing operations.

Our revenue for the foreseeable future will depend on the commercialization of MelaFind<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 the clinical trial and patient enrollment. We believe that period-to-period comparisons of our results of operations are not meaningful and should not be relied on as indicative of our future performance.

We commenced operations in December 1989 as a New York corporation and re-incorporated as a Delaware corporation in September 1997. Since our inception, we have generated significant losses. As of September 30, 2006, we had an accumulated deficit of \$28.9 million. We expect to continue to spend significant amounts on the development of MelaFind<sup>®</sup>. We expect to incur significant commercialization costs when we begin to introduce MelaFind<sup>®</sup> into the US market. On October 28, 2005, the Company completed an initial public offering. The Company issued 4,000,000 shares of common stock on October 28, 2005 and 262,300 shares of common stock on November 15, 2005, both issuances at \$5.00 per share.

After deducting underwriting discounts and expenses and estimated offering related expenses, the initial public offering resulted in net proceeds to the Company of approximately \$17.7 million. We will need to raise additional funds in order to achieve significant commercialization of MelaFind<sup>®</sup> and generate revenues.

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

Our research and development expenses incurred for the three and nine months ended September 30, 2006 were expenses related primarily to the development of MelaFind<sup>®</sup>. We expect to incur additional research and development expenses relating to MelaFind<sup>®</sup> prior to its commercial launch in the US and selected markets outside the US. Over the last nine months we have developed a relationship with a company named ASKION GmbH of Gera, Germany. ASKION has become an integral member of our MelaFind<sup>®</sup> development team and we expect to continue to work with ASKION for the foreseeable future. ASKION is currently preparing MelaFind<sup>®</sup> systems for our pivotal clinical trials that we expect to begin by year end 2006. These additional 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, these additional expenses could exceed our estimated amounts, possibly materially.

General and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with our efforts to obtain PMA approval for MelaFind<sup>®</sup> and toward development of a commercial infrastructure to market and sell MelaFind<sup>®</sup>. We anticipate that general and administrative expenses will increase as a result of the expected expansion of our operations, facilities and other activities associated with the planned expansion of our business, together with the additional costs associated with operating as a public company. We expect selling, general and administrative expenses to increase as we develop our sales and marketing capabilities to support placing MelaFind<sup>®</sup> in selected markets.

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

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

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

#### **Revenue Recognition**

We decided to discontinue all operations associated with our DIFOTI<sup>®</sup> product effective as of April 5, 2005 and account for the DIFOTI<sup>®</sup> revenue and expenses as a discontinued operation. Revenue from the DIFOTI<sup>®</sup> product sales had been recognized at the time of delivery and acceptance, after consideration of all the terms and conditions of the customer contract.

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

#### **Stock-Based Compensation and Deferred 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 and, consequently, has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options in 2006 includes:(1) quarterly amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, over the requisite service period based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*; and (2) 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 development milestones not under the Company's control. Upon the attainment of the relevant development 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 (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.* For equity instruments that are not immediately vested, compensation cost is measured on the date such instruments vest or a performance commitment is reached, as defined in EITF 96-18. Prior to the effective date of SFAS 123R, the Company recorded deferred compensation during the quarter the grant was issued for the entire option value based on the Black Scholes valuation model. Subsequently, the deferred compensation was adjusted each quarter until vesting occurred and the charge was taken. Deferred compensation attributable to non-vested options or restricted stock was reflected as a reduction of stockholders' equity. In accordance with SFAS 123R, deferred compensation is no longer allowed to be recorded for the unvested portion of options and warrants, and accordingly, during 2006, the Company eliminated the deferred compensation balance with a corresponding reduction in additional paid-in-capital. 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 accounting principles generally accepted in the US. This is done as of each balance sheet date in our financial statements.

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

As we work on developing MelaFind<sup>®</sup>, we continue to spend a majority of our time and money in research and development related activities. Overall spending has remained relatively consistent throughout the first nine months of 2006. We expect these trends to continue through the end of 2006. However, we would expect an increase in costs associated with the start, and during the continuation, of the pivotal clinical trials for MelaFind<sup>®</sup>.

Our overall general and administrative costs have grown over the prior year but have also remained relatively consistent during the first nine months of 2006.

#### Three Months Ended September 30, 2006 Compared to Three Months Ended September 30, 2005

#### **Research and Development Expense.**

Research and development expense for the three months ended September 30, 2006 was \$1,648 as compared with \$876 for the three months ended September 30, 2005. This increase was primarily attributable to an increase in personnel costs of \$192, product development activities including manufacturing of \$405, and preparation for clinical trials of \$94. These increases were partially offset by a decrease in consulting fees associated with our product development and regulatory related activities of \$37.

In addition, we recorded a share-based compensation charge of \$113 for research and development personnel for the three months ended September 30, 2006. This expense includes charges in accordance with SFAS 123R, which we implemented beginning January 1, 2006.

#### General and Administrative Expense.

General and administrative expense for the three months ended September 30, 2006 was \$929 as compared with \$492 for the three months ended September 30, 2005. The increase was due to a rise in personnel and related costs totaling \$55, an increase in professional and consulting fees totaling \$184, and an increase in rent, insurance and overhead of \$114 of which \$57 was attributable to higher insurance premiums for Director and Officer insurance coverage.

In addition, we recorded an \$82 share-based compensation expense during the three months ended September 30, 2006 spending as a result of the implementation of SFAS 123R.

#### Nine Months Ended September 30, 2006 Compared to Nine Months Ended September 30, 2005

Our nine month 2006 spending trend is consistent with the three month spending noted above.

#### Research and Development Expense.

Research and development expense for the nine months ended September 30, 2006 was \$5,654 as compared with \$2,422 for the nine months ended September 30, 2005. This increase was attributable to higher personnel and personnel related costs of \$338 as we increased our research and development programs, and increased product development activities of our MelaFind<sup>®</sup> product. Product development costs rose \$2,217 of which \$1,828 was spent with our development partner, ASKION. Our clinical studies and regulatory costs increased by \$61, and our outside consulting fees increased \$118.

In addition, we recorded a \$497 share-based compensation charge for certain research and development personnel for the nine months ended September 30, 2006. This expense includes charges in accordance with SFAS 123R, relating to the issuance of stock options.



#### General and Administrative Expense.

General and administrative expense for the nine months ended September 30, 2006 was \$3,093 as compared with \$1,488 for the nine months ended September 30, 2005. Higher costs associated with our status as a public company included increased professional, legal and consulting fees of \$693. We also had an increase of \$451 in our insurance and overhead costs, including increases in Director and Officer insurance coverage of \$181. Our reimbursement and pre-marketing efforts increased by \$152 and staff expansion increases totaled \$124

In addition, we recorded a \$186 share-based compensation charge in accordance with SFAS 123R.

#### Interest Income/Expense.

Interest income for the three and nine months ended September 30, 2006 was \$152 and \$505 respectively, as compared to an expense of \$3 and income of \$60 respectively, for the comparative periods in the previous year. This increase was directly attributable to an increase in cash and marketable securities generated as a result of our initial public offering on October 28, 2005.

#### Liquidity and Capital Resources (in thousands)

From inception, we have financed our operations primarily through the use of working capital from private placements of equity securities and by applying for and obtaining a series of National Institute of Health Small Business Innovative Research grants and similar grants. 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 in net proceeds. 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, 2006, we had \$10,597 in cash, cash equivalents and marketable securities as compared to \$18,505 at December 31, 2005. The decrease was a result of cash used in operating activities partially offset by interest income produced by our cash and marketable securities.

Our cash and cash equivalents at September 30, 2006 are liquid investments in money market funds with a commercial bank. Our marketable securities are debt securities with a maturity within six months and consist of investments in corporate bonds, short-term US Treasury obligations and federal agency notes.

#### **Cash Flows from Operating Activities.**

Net cash used in operations was \$7,495 for the nine months ended September 30, 2006. For the corresponding period in 2005 net cash used in operations was \$4,179. Cash used in operations was attributable to net losses after an adjustment for non-cash charges related to depreciation and share-based compensation, and other changes in operating assets and liabilities.

#### **Cash Flows from Investing Activities.**

Net cash used in our investing activities was \$1,480 for the nine months ended September 30, 2006 and was principally related to the purchase of investments of approximately \$999 and \$451 for the purchase of scientific equipment and leasehold improvements in support of our MelaFind<sup>®</sup> development. For the corresponding period in 2005, net cash provided by our investing activities was \$6,510 and was principally related to the redemption of investments. In addition, in 2005 we purchased fixed assets totaling \$116.

#### **Cash Flows from Financing Activities.**

Net cash provided by financing activities was \$69 for the nine months ended September 30, 2006 and reflects proceeds from the sale of common stock upon exercise of options. For the corresponding period in 2005, net cash used in financing activities was \$1,093 which was primarily deferred registration costs partially offset by proceeds from a stock subscription receivable and from the sale of common stock.

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

We face certain risks and uncertainties, which are present in many emerging medical device companies. At September 30, 2006, we had an accumulated deficit of \$28.9 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 clinical development team and 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>. In order to achieve significant commercialization of MelaFind<sup>®</sup> we will need to obtain additional funding. We believe that the net proceeds from our recently completed October 31, 2006 financing and our 2005 initial public offering, including our current cash, cash equivalents, marketable equity securities and interest we earn on these balances, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures allowing the Company to continue planned operations through mid 2008.

Existing cash and cash generated from our recently completed October 31, 2006 financing and our 2005 initial public offering may not be sufficient to satisfy the liquidity requirements necessary to commercially launch MelaFind® or to develop additional products. We will seek to sell additional equity or debt securities or obtain a credit facility. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of, delay or eliminate some or all of planned product research development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the development of medical devices such as MelaFind<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 payors, 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**

The following table summarizes our outstanding contractual obligations as of September 30, 2006 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Less than							More than	
	Total		1	1 year		<u>1-3 years</u> (dollars in thousands)		5 years	5 years
Operating leases	\$	882	\$	254	`\$	490	\$	138	_

Our long-term obligations are two non-cancelable operating leases for space expiring June 2009 and November 2010. The lease on 3,700 square feet of office and laboratory space expires in June 2009, and the lease on 2,800 square feet of office space expires November 2010. In May 2006, we leased an additional 1,250 square feet at our laboratory facility for three years also expiring June 2009.

In connection with the planned start of our clinical trials, we have committed to several clinical sites a total of approximately \$173 in contracts that do not exceed one year. These contracts are cancelable by us with up to 30 days prior notice.

#### **Related Party Transactions**

On March 24, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D. to be effective as of April 1, 2006. In connection with his ongoing engagement as a consultant, Dr. Wagner received a stock option grant of 50,000 shares of the Company's common stock which vests in full immediately upon commencement of the pivotal trial for MelaFind<sup>®</sup>. As Dr. Wagner is a consultant to the Company we utilize EITF 96-18 to account for this grant. Under this method, we calculate a charge based on the fair market value of the option at the end of each quarter and adjust that charge each subsequent quarter until the option vests. For the nine months ended September 30, 2006, unrecognized compensation for this grant was \$142.

In addition, on March 24, 2006, Dr. Wagner received another stock option grant of 49,500 shares of the Company's common stock which vests immediately. The Company recorded a \$161 compensation charge during the first quarter ended March 31, 2006. Refer to Notes 7 and 8 to our financial statements for further details.

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.

For a more detailed description of our related party transactions, see our financial statements and the related notes to our financial statements in Note 11.

#### **Off-Balance Sheet Arrangements**

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

#### **Recent Accounting Developments**

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

In October 2006, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 155, "Accounting for Certain Hybrid Financial Instrumentsan amendment of Statements No. 133 and 140" (FAS 155). FAS 155 is effective for fiscal years that begin on or after October 1, 2006 and would permit companies the option to use a fair value measurement for certain hybrid financial instruments that contain an embedded derivative that would otherwise require bifurcation under under FAS 133. The Company does not expect the adoption of FAS 155 to have a material impact on its financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109" (FIN 48), which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on our financial reporting, and we are currently evaluating the impact, if any, the adoption of FIN 48 will have on our disclosure requirements.

#### **Risk factors**

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information contained in this report. If any of the following risks actually occur, our business, financial condition and results of operations would suffer. In that case, the trading price of our common stock would likely decline and you might lose all or part of your investment in our common stock.

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

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

We currently do not have any commercialized products or any significant source of revenue. We have invested substantially all of our time and resources over the last five years in developing MelaFind<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 payors, or the level of reimbursement may be insufficient to support widespread adoption of MelaFind<sup>®</sup>;
- 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 end of 2007. If we are unable to develop, obtain regulatory approval for or successfully commercialize MelaFind<sup>®</sup>, we will be unable to generate revenue.

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

We do not have the necessary regulatory approvals to market MelaFind<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 PMA approval 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:



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- 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® to assist in determining the appropriateness of biopsies of suspicious pigmented skin lesions. Before submitting a PMA application (the final module), we must successfully complete a pivotal clinical trial to demonstrate that MelaFind® is safe and effective. Product development, including clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the trial may be inadequate to support approval of a PMA application. While we obtained a Protocol Agreement from the FDA, FDA approval of a Protocol Agreement does not mean that the FDA will consider the data gathered in the trial sufficient to support approval of a PMA application, even if the trial's intended endpoints are achieved. There may be unexpected findings, particularly those that may only become evident from the larger scale of the pivotal clinical trial, as compared with the smaller scale tests done to date. For example, we initiated a clinical trial at the end of 2004 and encountered several technical problems which required us to refine the MelaFind® system. The data obtained in the pivotal trial may not be sufficient to support the anticipated indication for use, and may not support a more limited indication for use. The occurrence of unexpected findings in connection with the pivotal trial or any subsequent clinical trial required by the FDA may prevent or delay obtaining PMA approval and may adversely affect coverage or reimbursement determinations. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or even years while the trials are conducted and the data acquired are submitted in an amendment to the PMA. If we are unable to complete the clinical trials necessary to successfully support the MelaFind® PMA application, our ability to commercialize MelaFind®, and our business, financial condition, and results of operations would be materially adversely affected, thereby threatening our ability to continue operations. On October 12, 2006 we announced that the FDA had informed the Company that when submitted, the MelaFind® PMA application would receive expedited review. Expedited review means that upon filing a PMA with the FDA, it is placed at the beginning of the FDA's review queue and receives additional review resources. While the expedited review could shorten the MelaFind® FDA approval process, we can give no assurances that this will be the case.

#### If MelaFind<sup>®</sup> is approved by the FDA, it may be approved only for narrow indications.

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

If we wish to modify MelaFind<sup>®</sup> after receiving FDA approval, including changes in indications or other modifications that could affect safety and effectiveness, additional approvals could be required from the FDA. We may be required to submit extensive pre-clinical and clinical data, depending on the nature of the changes. Any request by the FDA for additional data, or any requirement by the FDA that we conduct additional clinical studies, could delay the commercialization of MelaFind<sup>®</sup> and require us to make substantial additional research, development and other expenditures. We may not obtain the necessary

regulatory approvals to market MelaFind<sup>®</sup> in the US or anywhere else. Any delay in, or failure to receive or maintain, approval for MelaFind<sup>®</sup> could prevent us from generating revenue or achieving profitability, and our business, financial condition, and results of operations would be materially adversely affected.

## MelaFind <sup>®</sup> may not be commercially viable if we fail to obtain an adequate level of reimbursement by Medicare and other third party payors. The markets for MelaFind <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 payors.

The 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 payors are increasingly attempting to contain healthcare costs by limiting both the scope of coverage and the level of reimbursement of new medical devices, and as a result, they may not cover or provide adequate payment for the use of MelaFind<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 payors 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 payors provide adequate coverage and reimbursement for our products, some physicians may be discouraged from using them, and our sales would suffer.

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

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

Clinical studies in the US have been ongoing for over five years, and we have a Protocol Agreement with the FDA, but we have not conducted the pivotal clinical trial required for PMA approval. We initiated a

trial under the terms of the Protocol Agreement at the end of 2004. However, technical operational issues with the systems were experienced, requiring further refinement.

We are currently refining the hardware systems and expect to have new systems available in order to start the pivotal clinical trial in 2006. However, we cannot provide any assurances that we will have these systems available on a timely basis. In addition, the pivotal clinical trial and supporting clinical studies will require the involvement of larger numbers of clinical sites than we have previously engaged at any single time and the recruitment of large numbers of patients. If the clinical sites, which enroll patients on a best efforts basis, do not provide cases at rates anticipated for any reason (such as, for example, lower than forecasted clinical site productivity), we may face delays or may be unable to complete the development of MelaFind<sup>®</sup>.

#### Risk of delay in product development.

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

The final training of the classifier, required to be completed before the classifier is utilized as described above, is expected to take approximately two months. Accordingly, the classifier must be ready for final training two months before the end of the pivotal trial. For the classifier to be ready for final training, approximately 300 melanoma lesions are targeted to have been received. Therefore, in addition to acquiring the melanoma lesions required to complete the pivotal trial (approximately 100), we must have completed the acquisition of approximately 300 training melanoma lesions on schedule. Currently, approximately 275 melanoma lesions are in the training database. The current classifier has been trained on 221 of these melanoma lesions. Our schedule for the acquisition of these lesions is based upon the projected numbers of imaging devices to be located at participating sites, the projected productivity of those sites in terms of melanomas and other lesions biopsied per month, and the projected efficiency of the study pathologists in classifying the lesion slides presented for histological analysis (the microscopic examination of excised or biopsied tissue specimens) and reporting their results. If we are unable to produce and maintain a sufficient number of imaging devices at participating sites, if the clinicians do not maintain sufficient productivity, or if the pathologists do not produce reports with sufficient efficiency, then our ability to maintain our schedule will be adversely affected, the start or conclusion of the pivotal trial may be delayed, and the submission of the completed PMA will be delayed.

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

#### 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 nine months ended September 30, 2006 was \$8.2 million, and as of September 30, 2006, we had an accumulated deficit of approximately \$28.9 million. We expect our research and development expenses 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 increased due to the additional operational and regulatory responsibilities applicable to public companies. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

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

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates, higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.
- As a result, we may not be able to compete effectively against these companies or their products.

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

The precision optical imaging field is subject to rapid technological change and product innovation. MelaFind<sup>®</sup> is based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies. Companies in the medical device industry with significantly greater financial, technical, research, marketing, sales and distribution and other resources have expertise and interest in the exploitation of computer-aided diagnosis, medical imaging, and other technologies MelaFind<sup>®</sup> utilizes. Some of these companies are working on potentially competing products or therapies, including confocal microscopy (a type of scanning microscopy for 3-dimensional specimens, which produces blur-free images at various depths), various forms of spectroscopy (a study of the way molecules absorb and emit light), other imaging modalities, including molecular imaging in which tagged antibodies search for cancer cell antigens, and molecular and genetic screening tests. In addition, the National Institutes of Health and other supporters of cancer research are presumptively seeking ways to improve the diagnosis or treatment of melanoma by sponsoring corporate and academic research. There can be no assurance that one or more of these companies will not succeed in developing or marketing technologies and products or services that demonstrate better safety or effectiveness, superior clinical results, greater ease of use or lower cost than MelaFind<sup>®</sup>, or that such competitors will not succeed in obtaining regulatory approval for introducing or commercializing any such products or services prior to us. FDA approval of a commercially viable alternative to MelaFind<sup>®</sup> produced by a competitor could significantly reduce market acceptance of MelaFind<sup>®</sup>.



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Any of the above competitive developments could have a material adverse effect on our business, financial condition, and results of operations. There is no assurance that products, services, or technologies introduced prior to or subsequent to the commercialization of MelaFind<sup>®</sup> will not render MelaFind<sup>®</sup> less marketable or obsolete.

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

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

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

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

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

Even if Medicare covers a device for certain uses, that does not mean that the level of reimbursement will be sufficient for commercial success. We expect to experience pricing pressures in connection with the commercialization of MelaFind<sup>®</sup> and our future products due to efforts by private and government-funded payors to reduce or limit the growth of healthcare costs, the increasing influence of health maintenance organizations, and additional legislative proposals to reduce or limit increases in public funding for healthcare services.

Private payors, including managed care payors, increasingly are demanding discounted fee structures and the assumption by healthcare providers of all or a portion of the financial risk. Efforts to impose greater discounts and more stringent cost controls upon healthcare providers by private and public payors are expected to continue. Payors frequently review their coverage policies for existing and new diagnostic tools and can, sometimes without advance notice, deny or change their coverage policies. Significant limits on the scope of services covered or on reimbursement rates and fees on those services that are covered could

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have a material adverse effect on our ability to commercialize MelaFind<sup>®</sup> and therefore, on our liquidity and our business, financial condition, and results of operations.

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

#### MelaFind<sup>®</sup> may never achieve market acceptance even if we obtain regulatory approvals.

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

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

The identification and screening of melanomas is now dominated by visual clinical evaluation, with a minority of dermatologists using dermoscopy. Even if MelaFind<sup>®</sup> proves to be as effective as visual inspection by an expert dermatologist, and if all approvals are obtained, the success of MelaFind<sup>®</sup> will depend upon the acceptance by dermatologists and other physicians who perform skin examinations and treat skin disorders, including industry opinion leaders, that the diagnostic information provided by MelaFind<sup>®</sup> is medically useful and reliable. We will be subject to intense scrutiny before physicians will be comfortable incorporating MelaFind<sup>®</sup> in their diagnostic approaches. We believe that recommendations by respected physicians will be essential for the development and successful marketing of MelaFind<sup>®</sup>, and there can be no assurance that any such recommendations will be obtained.

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



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

Our operations have consumed substantial amounts of cash for each of the last six years. We currently believe that our available cash, cash equivalents and marketable securities, including the proceeds from our recently completed October 31, 2006 financing and our 2005 initial public offering, will be sufficient to fund our anticipated levels of operations through mid 2008. However, our business or operations may change in a manner that would consume available resources more rapidly than we anticipate. We expect to continue to spend substantial amounts on research and development, including conducting a clinical trial for MelaFind<sup>®</sup>. We will need additional funds to fully commercialize the product, including development of a direct sales force and expansion of manufacturing capacity. We expect that our cash used by operations will increase significantly in each of the next several years, and should we encounter any material delays or impediments, we may need additional funds to complete the development of MelaFind<sup>®</sup> and commence commercialization of MelaFind<sup>®</sup>, and we will need additional funds to achieve significant commercialization of MelaFind<sup>®</sup>. 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 payors, 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.

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

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

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

We do not have a sales organization and have no experience as a company in the marketing and distribution of devices such as MelaFind<sup>®</sup>. To achieve commercial success for MelaFind<sup>®</sup>, we must develop a sales and marketing force and enter into arrangements with others to market and sell our products. Following product approval, we currently plan to establish a small direct sales force to market MelaFind<sup>®</sup> in the US, focused on introducing it at high volume dermatologists' offices and training their staff in its use, but we have not made any final determinations regarding the use of a particular marketing channel. We anticipate that we will need additional funds in order to implement this marketing plan. In addition to being expensive, developing such a sales force is time consuming and could delay or limit the success of any product launch.



We may not be able to develop this capacity on a timely basis or at all. Qualified direct sales personnel with experience in the medical device market are in high demand, and there is no assurance that we will be able to hire or retain an effective direct sales team. Similarly, qualified, independent medical device representatives both within and outside the US are in high demand, and we may not be able to build an effective network for the distribution of our product through such representatives. We have no assurance that we will be able to enter into contracts with representatives on terms acceptable or reasonable to us. Similarly, there is no assurance that we will be able to build an alternate distribution framework, should we attempt to do so.

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

## We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing capabilities are insufficient to produce an adequate supply of MelaFind<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 certain production aspects to contract manufacturers. Any difficulties in the ability of third-party manufacturers to supply devices of the quality, at the times, and in the quantities we need, could have a material adverse effect on our business, financial condition, and results of operations.

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

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

Our manufacturing efforts currently rely on FillFactory, a subsidiary of Cypress Semiconductor Corp., to manufacture and supply the complementary metal oxide semiconductor sensor in MelaFind<sup>®</sup>, on Carl Zeiss Jena GmbH (Zeiss) for lenses and lens objective assemblies, on ASKION GmbH (ASKION) for the main subassembly and on Fairchild Semiconductor Corp., Panasonic Corp., Roithner-Laser Vienna, CompServ and others for light-emitting diodes, or LEDs, printed circuit boards, and other elements or components of our devices. We have written agreements with several of these vendors, under which the vendor is obligated to perform services or produce components for us. There can be no assurance that these third parties will meet their obligations under the agreements. Each of these suppliers is a sole-source supplier. Our contract manufacturers also rely on sole-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to procure their raw material on time, failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- suppliers may make errors in manufacturing components that could negatively affect the effectiveness or safety of our products, or cause delays in shipment of our products;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- we may have difficulty locating and qualifying alternative suppliers for our sole-source suppliers;
- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

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

We have entered into a development agreement with ASKION to complete developmental engineering and testing of our hand-held imaging device, and have also entered into a production agreement with ASKION to assemble the components and produce initial quantities of our hand-held imaging devices for clinical trials. We intend to enter into a contract for commercial production of the hand-held imaging devices once specifications for MelaFind® have been finalized, but we may not be able to enter into such an agreement on mutually acceptable terms. Failure to enter into such an agreement with ASKION would require us to expand our own manufacturing facilities or obtain such services elsewhere. Similarly, we have entered into a confidentiality agreement and a development agreement with Carl Zeiss Jena GmbH for lens objective assemblies, and we have entered into a contract for limited production of the lenses. The manufacturing agreement with ASKION includes integration of these lenses in the hand-held imaging devices. Our planned reliance upon an outside provider for assembly and production services subjects us to the risk of adverse consequences from delays and defects caused by the failure of such outside supplier to meet its contractual obligations, including confidentiality obligations in the case of Carl Zeiss Jena GmbH, which is

an affiliate of Carl Zeiss AG, a potential competitor. The failure by us or our supplier to produce a sufficient number of hand-held imaging devices that can operate according to our specifications could delay the pivotal clinical trial and/or the commercial sale of MelaFind<sup>®</sup> and would adversely affect both our ability to successfully commercialize MelaFind<sup>®</sup> and our business, financial condition and results of operations.

## 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 Regulation.

We are in the process, but have not yet successfully completed, all the steps necessary to verify and validate the design of the MelaFind® system that are required to be performed prior to commercialization. If we are delayed or unable to complete verification and validation successfully, we will not be able to sell MelaFind®, and we will not be able to meet our plans for the commercialization of MelaFind® in late 2007. Assuming that regulatory approval of MelaFind® is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or effectiveness of the device. Later discovery of previously unknown problems with MelaFind®, including manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in restrictions on MelaFind® or its manufacturing processes, withdrawal of MelaFind® from the market, patient or physician notification, voluntary or mandatory recalls, fines, withdrawal of regulatory approvals, refusal to approve pending applications or supplements to approved applications, refusal to permit the import or export of our products, product seizures, injunctions or the imposition of civil or criminal penalties. Should any of these enforcement actions occur, our business, financial condition and results of operations would 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. We have discussed the findings in a subsequent meeting with the FDA and are in the process of addressing the deficiencies. However, on May 18, 2006 the FDA visited the Company's facility for a follow-up inspection. No non-conformities or negative observations were reported to the Company. We continue to work with consultants to address the inspectional findings, particularly as they relate to current MelaFind® design development and ultimate MelaFind® commercial manufacturing. If we are not successful in convincing the FDA that we are capable of addressing its concerns, or if our efforts to address the deficiencies should prove unsuccessful, we might be subject to additional FDA action of a type described below, which could negatively affect our ability to commercialize MelaFind®. There can be no assurance that the future

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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.

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

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

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

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

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



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

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

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and the Civil Monetary Penalties Law, which authorizes HHS to impose civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use of MelaFind® by physicians may dissuade physicians from either purchasing or using MelaFind® and could have a material adverse effect on our ability to commercialize MelaFind®.

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

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



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

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

Any infringement or misappropriation claim could cause us to incur significant costs, place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign MelaFind® to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees.

These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing MelaFind<sup>®</sup>, and/or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

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

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

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

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

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

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

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

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

The success of MelaFind<sup>®</sup> is dependent upon our ability to protect our data center against damage from fire, power loss, telecommunications failure, natural disaster, sabotage or a similar catastrophic event. Substantially all of our computer equipment and data operations are located in a single facility. Our prospective failure to maintain off-site copies of information contained in our MelaFind<sup>®</sup> database, or our inability to use alternative sites in the event we experience a natural disaster, hardware or software malfunction or other interruption of our data center, or any interruption in the ability of physicians to obtain access to our MelaFind<sup>®</sup> server and its database could adversely impact our business, financial condition and results of operations.

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

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

and security regulations, the potential violation of which may trigger concerns by healthcare providers, which may adversely impact our business, financial condition and results of operations.

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

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

We plan to use the internet as a medium to provide diagnostic assistance services to physicians. We also plan to use the internet to inform the public about the availability of our products and to market to and communicate with physicians who are potential or actual customers. Our success will therefore depend in part on the continued growth and use of the internet. If our ability to use the internet fails, it may materially adversely affect our business.

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

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

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

All of our operations are conducted at two adjacent buildings in Irvington, New York. We take precautions to safeguard our facility, including insurance, health and safety protocols, contracted off-site engineering services, provision for off-site manufacturing, and storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

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

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

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

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

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

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

We are highly dependent on our senior management, especially Joseph V. Gulfo, M.D., our President and Chief Executive Officer, Gerald Wagner, Ph.D., our Acting Chief Operating Officer and Dina Gutkowicz-Krusin, Ph.D., our Director of Clinical Studies. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as scientists, clinicians, engineers, and experienced sales and marketing individuals, is intense, and we may not be able to retain our personnel. The loss of the services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the development and introduction of MelaFind<sup>®</sup>. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement. Each of our officers may terminate their employment at any time without notice and without cause or good reason.

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

### Our financial results for future periods may be adversely affected by changes required by financial and accounting regulatory agencies.

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

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

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

## If we fail to maintain the adequacy of our internal controls, our ability to provide accurate financial statements could be impaired and any failure to maintain our internal controls and provide accurate financial statements could cause our stock price to decrease substantially.

We face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 (SOX), as well as new rules subsequently implemented by the SEC, the Public Company Accounting Oversight Board and the NASDAQ Capital Market, require changes in the corporate governance practices of public companies. We expect these new rules and regulations to increase our legal and financial compliance costs, to divert management attention from operations and strategic opportunities, and to make legal, accounting and administrative activities more time-consuming and costly. We have incurred substantially higher costs to maintain directors' and officers' insurance since becoming a public company.

We are in the process of instituting changes to our internal procedures to satisfy the requirements of the SOX. We have retained a consultant to assist us and are currently evaluating our internal controls systems in order to allow us to report on, and our independent registered public accounting firm to attest to, our assessment of our internal controls as they relate to financial reporting, as required by Section 404 of the SOX. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 of the SOX in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations, since there is no precedent available by which to measure compliance adequacy. As a small company with limited capital and human resources, we will need to divert management's time and attention away from our business in order to ensure compliance with these regulatory requirements. As a public company, we require greater financial resources than we required as a private company. Implementing these changes may require new information technologies systems, the auditing of our internal controls as such standards are modified, supplemented or amended from time to time, we may not be able to provide accurate financial statements and comply with the SOX. Any failure to maintain the adequacy of our internal controls and provide accurate financial statements could cause the trading price of our common stock to decrease substantially.

#### **Risks Relating to our Common Stock**

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

Prior to our initial public offering, there was no public market for our common stock. An active public market for our common stock may not continue to develop or be sustained. Further, we cannot be certain that the market price of our common stock will not decline below the initial public offering price or below the amount required by NASDAQ to maintain a listing on its Capital Market. Should we fail to meet the minimum standards established by NASDAQ for its Capital Market, we could be de-listed, meaning shareholders might be subject to limited liquidity.

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

Our stock price is likely to be volatile. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:



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- results of our research and development efforts and our clinical trials;
- the timing of regulatory approval for our products;
- failure of any of our products, if approved, to achieve commercial success;
- the announcement of new products or product enhancements by us or our competitors;
- regulatory developments in the US and foreign countries;
- ability to manufacture our products to commercial standards;
- developments concerning our clinical collaborators, suppliers or marketing partners;
- changes in financial estimates or recommendations by securities analysts;
- public concern over our products;
- developments or disputes concerning patents or other intellectual property rights;
- product liability claims and litigation against us or our competitors;
- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of and third-party reimbursement in the US and other countries;
- changes in accounting principles or practices;
- general economic, industry and market conditions; and
- future sales of our common stock.

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

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

As of September 30, 2006, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates in the aggregate beneficially owned approximately 44% of our outstanding common stock. As a result, these stockholders, subject to any fiduciary duties owed to our other stockholders under Delaware law, will be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your interests. The concentration of ownership could delay or prevent a change in control of our company or otherwise discourage a potential acquirer from attempting to obtain control of our company, which in turn could reduce the price of our common stock. In addition, these stockholders, some of whom have representatives sitting on our board of directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes of control of our company, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

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

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that these sales may occur, the market price of our common stock could decline significantly. At September 30, 2006, we had 10,952,602 shares of common stock outstanding. All of the shares offered in our initial public offering completed on November 2, 2005 are freely tradable without restriction or further registration under the federal securities laws, unless purchased by our affiliates. Beginning October 27, 2006 all of our common stock issued prior to our initial public offering to non-affiliates became available for sale under Rule 144(k).

In connection with our October 31, 2006 private placement, our directors and key officers entered into lock-up agreements providing that they will not sell or otherwise dispose of, without the prior written consent of Jefferies & Company, Inc., any shares, options or warrants to acquire shares of, or securities exchangeable or exercisable for or convertible into, our common stock for a period continuing through the earlier of (x) the 150th day following November 3, 2006 and (y) 30 days after our registration statement to be filed in connection with the private placement is declared effective by the SEC.

On July 31, 2006, we registered 1,899,875 shares of common stock on form S-8 that are authorized for issuance under our stock option plans. We intend to register up to 325,135 shares of our common stock available for issuance pursuant to our 2005 stock option plan on Form S-8 in the fourth quarter of 2006 or thereafter. We intend to register additional shares of our common stock on Form S-8 to the extent necessary to cover any additional shares that may be authorized for issuance under our stock option plans by our board of directors (or compensation committee) in accordance with the terms of our stock option plans. As of September 30, 2006, 1,571,934 shares were subject to outstanding options, of which 532,524 shares were vested.

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

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

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

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

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



#### ITEM 3.

## Quantitative and Qualitative Disclosures about Market Risk

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

### ITEM 4.

#### **Controls and Procedures**

### Evaluation of disclosure controls and procedures

Based on their evaluation as of September 30, 2006, our Chief Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were sufficiently effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form IO-Q.

#### Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2006 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.

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

Not applicable

#### Item 3. Defaults Upon Senior Securities.

Not applicable.

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

None



#### Item 5. Other Information.

(a) William R. Bronner resigned as our Secretary and Vice President, Legal Counsel and Compliance, effective as of November 9, 2006. Our Board of Directors appointed Richard Steinhart, the Company's Vice President of Finance and Chief Financial Officer as Secretary to replace Mr. Bronner as Secretary. In connection with Mr. Bronner's resignation, we entered into a letter agreement dated November 9, 2006 regarding the terms of his resignation (the "Resignation Agreement").

Pursuant to the Resignation Agreement, Mr. Bronner will (i) continue as an employee through November 30, 2006 at his current salary, (ii) be engaged as a consultant for a period of thirteen months, commencing December 1, 2006, at an annual rate of \$50,000 and (iii) receive a lump sum payment of \$50,000 during the first week of January, 2007 as consideration for all vacation and other personal time and compliance with the terms of the Resignation Agreement. Mr. Bronner is entitled to exercise his stock options to purchase up to 78,535 shares of our common stock previously granted to him pursuant to our stock incentive plans for a period of ninety days following November 30, 2006. All such stock options that are subject to vesting will become fully vested as of November 30, 2006. The Resignation Agreement contains a general release from Mr. Bronner, the effectiveness of which is subject to statutory review and revocation periods. In addition, the Resignation Agreement contains certain mutual non-disparagement covenants.

(b) Not applicable.

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#### Item 6. Exhibits

- 3.1 Fourth Amended and Restated Certificate of Incorporation. (1)
- 3.2 By-laws. (2)
- 4.1 Specimen Common Stock Certificate. (2)
- 4.2 Specimen Warrant Certificate (incorporated by reference from Exhibit 4.3). (3)
- 4.3 Form of Warrant Agreement entered into by and between the Registrant, ThinkEquity Partners LLC and Stanford Group Company. (3)
- 4.4 Form of Warrant. (4)
- 10.1 Production Agreement between the Registrant and Askion GmbH dated as of January 25, 2006. (4)
- 10.2 Amended and Restated Consulting Agreement effective as of April 1, 2006 between the Registrant and Gerald Wagner. (5)
- 10.3 Resignation Agreement, dated April 24, 2006, between the Registrant and Karen Krumeich. (6)
- 10.4 Employment Offer Letter, dated April 24, 2006, between the Registrant and Richard I. Steinhart. (6)
- 10.5 Employment Offer Letter, dated May 30, 2006, between the Registrant and Christiano S. Butler. (7)
- 10.6 Securities Purchase Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of October 31, 2006. (9)
- 10.7 Securities Purchase Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of October 31, 2006. (9)
- 10.8 Registration Rights Agreement among the Registrant and the purchasers identified on the signature pages thereto, dated as of October 31, 2006. (9)
- 10.9 Placement Agency Agreement by and between the Registrant and Jefferies & Company, Inc., dated as of October 31, 2006. (10)
- 10.10 Resignation Agreement, dated November 9, 2006, between the Registrant and William R. Bronner.
- 31.1 Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
- 31.2 Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (1) Previously filed in connection with Amendment No. 1 to Electro-Optical Sciences, Inc. Registration Statement on Form S-1 (file No. 333-125517) filed on July 15, 2005.
- (2) Previously filed in connection with Amendment No. 2 to Electro-Optical Sciences, Inc. Registration Statement on Form S-1 (file No. 333-125517) filed on August 8, 2005.
- (3) Previously filed in connection with Amendment No. 4 to Electro-Optical Sciences, Inc. Registration Statement on Form S-1 (file 333-125517) filed on September 27, 2005, as an exhibit to the Form of Underwriting Agreement.
- (4) Previously filed in connection with Registrant's Form 8-K filed on November 1, 2006.
- (5) Previously filed in connection with Registrant's Form 8-K filed in January 31, 2006.
- (6) Previously filed in connection with Registrant's Annual Report on Form 10-K filed on March 29, 2006 as Exhibit 10.17 thereto.
- (7) Previously filed in connection with Registrant's Form 8-K filed on April 27, 2006.
- (8) Previously filed in connection with Registrant's Form 8-K filed on June 2, 2006.
- (9) Previously filed in connection with Registrant's Form 8-K filed on November 8, 2006.
- (10) Previously filed in connection with Registrant's Form 8-K filed on November 1, 2006.

## 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 & Chief Financial Officer (Principal Financial and Accounting Officer)

Date: November 14, 2006

#### EXHIBIT INDEX

- Exhibit Number 10.10 Description Resignation Agreement, dated November 9, 2006, between the Registrant and William R. Bronner. 31.1 Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934
  - 31.2 Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934
  - 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002



November 9, 2006

William Bronner, Esq. 1325 Croton Dam Road Ossining, NY 10562

Dear Bill:

We recognize that, over the years, you have provided significant value to Electro-Optical Sciences, Inc. We understand that, now that the company is in a more mature position, you would like to devote a significant amount of your time to other endeavors but would be willing to support the company on a more limited basis.

We therefore would like to offer you a thirteen month consulting agreement, effective as of December 1, 2006, on a one day per week basis in consideration of monthly payments based on an annual rate of \$50,000. Your day of work per week shall be conducted off premises on a day chosen by you unless otherwise requested by the company, upon reasonable advance notice and with due regard for the need to accommodate potential conflicts in schedule, including vacation, that you be present at EOS' headquarters in Irvington, New York or that your assistance is needed on a certain day for any week. You may travel and incur routine out-of-pocket expenses at the request of EOS' management, but very little travel is anticipated.

Reporting to the President & Chief Executive Officer, and working with the Chief Financial Officer and Chief Operating Officer, you will assist the company in certain of its contractual and administrational matters as assigned to you by management. Such services will include matters relating to EOS' facilities, purchasing matters, intellectual property administration, quality work and documentation, insurance matters and other matters and tasks, as assigned by management, consistent with the limited scope of your arrangement. You will continue to be bound by EOS' standard operating policies and procedures.

We will confirm acceptance of your resignation effective as of the date of this letter from all offices held by you at EOS, including without limitation, Vice President and Corporate Secretary. We will continue to employ you at your current salary for 4 days' work per week through November 30, 2006 at which time your employment with the Company shall terminate. You shall be deemed to have worked 32 hours per week, holidays excepted, throughout November 2006, regardless of your actual presence in the EOS facilities.

Although you are not otherwise entitled to severance pay or any similar payment on account of termination of your employment with EOS, as consideration for all vacation or other personal time and similar accruals to which you may have been entitled in connection with your employment through the date of termination, the consulting services to be provided hereunder and for your execution of and compliance with the other terms of this Agreement, EOS agrees to pay to you a single lump sum payment of \$50,000 during the first week of January, 2007.

Your coverage under all of EOS' health and welfare plans (dental and life insurance, short term disability, long term disability, accidental death and dismemberment insurance) will terminate on November 30, 2006 provided that you shall be eligible to elect continued health coverage

with EOS pursuant to the provisions of the Consolidated Omnibus Reconciliation Act of 1985 (as amended, "COBRA"), and the requirements and limitations thereof.

As noted above, unless extended by you and the company, this consulting arrangement will terminate on December 31, 2007, provided, however, that your consulting arrangement may be terminated at any time by the company for "Cause" which shall mean for purposes hereof (i) an act of fraud or misappropriation by you, (ii) a material breach by you of a fiduciary responsibility owing to EOS (iii) your habitual failure to perform your duties hereunder and failure to cure within ten business days of receipt of notice or (iv) your becoming permanently disabled and incapable of performing your duties hereunder. In addition, you may terminate this agreement without giving a reason on 15 days prior written notice given to the President of EOS.

Immediately upon execution of this Agreement, you shall (i) return all personal property provided to you by EOS in connection with the performance of your duties as an employee of EOS, including, without limitation, all keys, card keys, identification cards and credit cards, and all other property of EOS in your possession;) and (ii) as requested by EOS, return all materials containing confidential information including, without limitation, all confidential information as defined in the Employee Invention, Non-Disclosure and Non-Competition Agreement dated July 1, 2000 between you and EOS and the Confidentiality Agreement dated October 6, 1999 between you and EOS, both as attached as Exhibit A hereto (collectively, the "Confidentiality Agreements") and all memoranda, books, papers, letters, customer lists, processes, computer software, records, financial information, policy and procedure manuals, training and recruiting procedures and other data, and all copies thereof and therefrom, in any way relating to EOS' business and affairs. You shall have the use of the portable computer you have been using, until termination of your consulting with us provided that EOS shall have an opportunity to remove all company data files from the hard drive of such computer in a manner that does not adversely affect the operation of the application software installed on such computer. Your access to the company's computer system, your present email account and telephone extension shall be terminated as of the date of this letter provided that the company will forward to you emails and messages received on your behalf through November 30, 2006. During your consulting with EOS you may provide services to any client other than an actual or probable competitor of EOS, consistent with your obligations as described herein and in the consulting agreement.

EOS will provide appropriate affirmative employment references if requested. Management will provide reasonable support of your transition activities, including recommendations, and will not object to your contact with members of the Board of Directors regarding their knowledge of opportunities for you to provide services for other entities unrelated to EOS. However you will not engage in other contact with the Board of Directors (other than in their capacities as executive officers of the company) other than at the request of EOS' management or at the initiative of the Director in question.

The attached <u>Schedule A</u> contains a true and complete list of all equity interests in EOS which you own or have any legal interest in. You will continue to be eligible to exercise your stock options in accordance with their terms. In addition, the company will accelerate the vesting provisions in all of your stock options such that they will all be vested as of November 30, 2006. You acknowledge and agree that you will continue to be bound by the Confidentiality Agreements.

In consideration of the payments and benefits set forth herein, each party voluntarily, knowingly and willingly releases and forever discharges the other party and its affiliates, together with each of Eos and its entities' respective officers, employees, agents, fiduciaries, employee benefit plans and administrators and all of their predecessors, successors and assigns (collectively, the "Releasees") from any and all claims and rights of any nature whatsoever which you or they now have or in the future may have against them or you. This release includes, but is not limited to, any rights or claims relating in any way to your employment relationship with EOS or any of the other Releasees any rights or claims relating in any way to the termination of your employment, any contract claims (express or implied, written or oral), or any rights or claims arising under any statute, including, without limitation, the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Older Workers' Benefit Protection Act, the Rehabilitation Act of 1973 (including Section 504 thereof), the Family Medical Leave Act, Title VII of the 1964 Civil Rights Act, the Civil Rights Act of 1866 (42 U.S.C. § 1981), the Civil Rights Act of 1991, the Equal Pay Act, the Fair Labor Standards Act, the National Labor Relations Act, the Worker Adjustment and Retraining Notification Act of 2002 (the Sarbanes-Oxley Act), all as amended, all laws relating to violation of public policy, retaliation, or interference with legal rights; whistleblower claims; any tort, fraud or constitutional claims; and any other federal, state or local law. This release specifically includes, but is not limited to, any claims based upon the right to the payment of wages, vacation, pension benefits, stock options or equity interests, any other employee benefits, or any other rights arising under federal, state or local laws prohibiting discrimination and/or harassment on the basis of race, color, age, religion, sex, national origin, sexual orientation, military status, physical or mental disability, marital status or domestic partnership status, genetic information, harassment or any other basis prohibited by law. Notwithstanding the foregoing this release shall not include any claims pertaining to benefits provided by this agreement, including the schedules attached hereto, and rights, if any, to government-provided unemployment benefits, or rights, if any, to vested retirement benef

Neither party shall make, or cause to be made, any negative or disparaging statements express or implied, whether in writing, orally, or through the use of any other communications medium about, or to engage in any other conduct or course of conduct of any nature which would result in an injury (whether monetary or otherwise) to you, EOS, the Releasees, or collectively their services, reputation, financial status, business relationships, or any of their directors, officers or employees.

This Agreement shall be governed by the law of the State of New York without regard to New York's law of conflicts and may not be changed, and a waiver may only be enforced, unless the changes and/or waiver are in writing and signed by you and the President of EOS. Should any provision of this Agreement be held invalid, or invalid as applied, the remainder of this Agreement, or the application of such provision to persons or circumstances other than those as to which it is held invalid, shall not be affected.

This Agreement constitutes the entire agreement between you and EOS of any kind whatsoever and supersedes all other agreements between you and EOS, if any, which shall be considered void and of no force and effect, except that (i) this Agreement shall not relieve you of any contractual or common law obligations to maintain EOS' confidential, proprietary and trade secret information as confidential and not to use such information for your benefit or the benefit of any third party, (ii) this Agreement does not supersede the stock option agreements listed on the Schedules to this Agreement or the Confidentiality Agreements and (iii) the existing corporate indemnity and insurance for claims based on past actions as an officer of EOS, provided under the Agreement of Indemnity and the Directors and Officers' insurance policies.

By signing this Agreement, you acknowledge that (a) you have carefully read and understand this Agreement; (b) EOS advised you to consult with an attorney and/or any other advisors of your choice before signing this Agreement; (c) you understand that this Agreement is

**LEGALLY BINDING** and by signing it you give up certain rights, including any right to bring an age discrimination claim under the Age Discrimination in Employment Act; (d) you have voluntarily chosen to enter into this Agreement and have not been forced or pressured in any way to sign it; and (e) you acknowledge and agree that the benefits set forth in this Agreement are contingent on execution of this Agreement, which releases all of your claims against EOS, and you **KNOWINGLY AND VOLUNTARILY AGREE TO RELEASE** EOS and the Releasees from any and all claims you may have, known or unknown, in exchange for the benefits you have obtained by signing, and that these benefits are in addition to any benefit you would have otherwise received if you did not sign this Agreement.

You have twenty-one (21) days to review, sign and return this Agreement to my attention at EOS after which time this offer will be withdrawn. You may revoke the Agreement at any time up to seven (7) days after you have signed the Agreement by written notice of such revocation delivered to me within such seven day period. You will not receive any payment or other benefits under this Agreement until after this revocation period has passed.

Sincerely,

/s/ Richard I. Steinhart Richard I. Steinhart Vice President & Chief Financial Officer

ACCEPTED AND AGREED:

/s/ William Bronner William Bronner Date: 11/09/06

## <u>Schedule A</u> William Bronner list of options

Schedule of Options Name	Plan or Source	Grant Date	Expiration Date	Exercise Price	10/31/06 Outstanding	10/31/06 Vested
William Bronner	1996 Stock Option Plan	02/19/02	02/19/12	\$1.00	1,875	1,500
William Bronner	1996 Stock Option Plan	02/02/04	02/02/09	\$0.46	17,000	17,000
William Bronner	2003 Stock Incentive Plan	12/17/04	12/17/09	\$0.46	20,000	20,000
William Bronner	1996 Stock Option Plan	01/15/03	01/15/13	\$1.00	32,160	32,160
William Bronner	2005 Stock Option Plan	05/22/06	05/22/11	\$7.08	7,500	—
Totals					78,535	70,660

## <u>Exhibit A</u>

Employee Invention, Non-Disclosure and Non-Competition Agreement dated July 1, 2000

Confidentiality Agreement dated October 6, 1999

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

I, Joseph V. Gulfo, certify that:

- 1. I have reviewed this report on Form 10-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 14, 2006

/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) UNDER THE SECURITIES EXCHANGE ACT OF 1934

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 14, 2006

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

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 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, 2006 (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 14, 2006

/s/ Richard I. Steinhart

Richard I. Steinhart Vice President & Chief Financial Officer (Principal Accounting and Financial Officer) November 14, 2006

\*A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Electro-Optical Sciences, Inc. and will be retained by Electro-Optical Sciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This written statement accompanies the Form 10-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.