

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2005

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

For the transition period from to

Commission file number 333—125517

ELECTRO-OPTICAL SCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

13-3986004

(I.R.S. Employer
Identification No.)

**3 West Main Street, Suite 201
Irvington, New York**

(Address of Principal Executive offices)

10533

(Zip Code)

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No *

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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

As of November 15, 2005, 10,785,464 shares of the Registrant's common stock were outstanding.

* The registrant has not been subject to the filing requirements for the past 90 days as it commenced trading following its initial public offering on October 28, 2005, but has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 since such time.

**Electro-Optical Sciences, Inc.
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Item 1. Unaudited Financial StatementsELECTRO-OPTICAL SCIENCES, INC.
BALANCE SHEETS

	September 30, 2005 (unaudited)	December 31, 2004 *
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 1,345,773	\$ 108,705
Marketable securities	—	6,594,751
Accounts receivable, net	—	7,128
Inventories	—	69,755
Prepaid expenses and other current assets	5,779	32,844
Assets held for sale	156,677	—
Deferred registration costs	1,836,610	—
Total Current Assets	3,344,839	6,813,183
Property and equipment, net	180,095	89,306
Patents and trademarks, net	84,041	163,459
Other assets	33,612	30,201
Total Assets	\$ 3,642,587	\$ 7,096,149
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities:		
Accounts payable (includes related parties \$26,258 as of September 30, 2005 and \$2,000 as of December 31, 2004)	\$ 302,813	\$ 338,821
Accrued expenses	303,096	228,583
Accrued registration costs	701,488	—
Deferred revenues	—	106,335
Other current liabilities	10,876	17,284
Total Current Liabilities	1,318,273	691,023
REDEEMABLE CONVERTIBLE PREFERRED STOCK		
Redeemable Preferred Stock Series B convertible 992,986 shares designated (liquidation preference \$2.26 per share); issued and outstanding 992,986 shares at September 30, 2005 and December 31, 2004	2,244,147	2,244,147
Redeemable Preferred Stock Series C convertible 5,744,340 shares designated (liquidation preference \$2.26 per share); issued and outstanding 5,414,779 shares at September 30, 2005 and December 31, 2004	8,680,769	7,711,027
COMMITMENTS AND CONTINGENCIES		
Stockholders' Deficiency:		
Preferred stock — \$.10 par value; authorized 16,936,704 shares: Series A Convertible Preferred Stock, 199,380 shares designated — (liquidation preference \$5.00 per share); issued and outstanding 198,000 shares at September 30, 2005 and December 31, 2004	972,311	972,311
Common stock — \$.001 par value; authorized 30,000,000 shares; issued and outstanding 3,125,079 shares at September 30, 2005 and 1,809,758 shares at December 31, 2004	3,125	1,810
Additional paid-in capital	8,718,136	9,611,094
Notes receivable for stock subscriptions	—	(69,000)
Deferred compensation	(135,405)	(159,300)
Accumulated deficit	(18,158,769)	(13,906,963)
Stockholders' Deficiency	(8,600,602)	(3,550,048)
Total Liabilities and Stockholders' Deficiency	\$ 3,642,587	\$ 7,096,149

See accompanying notes to the financial statements

*Derived from the audited balance sheet as of December 31, 2004

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Operating expenses:				
Research and development	876,193	422,509	2,422,017	1,115,561
General and administrative	491,976	203,567	1,487,907	842,646
Operating loss from continuing operations	<u>(1,368,169)</u>	<u>(626,076)</u>	<u>(3,909,924)</u>	<u>(1,958,207)</u>
Interest income	2,574	(530)	(60,195)	(1,073)
Interest expense	—	900	—	83,240
	<u>2,574</u>	<u>370</u>	<u>(60,195)</u>	<u>82,167</u>
Loss from continuing operations	(1,370,743)	(626,446)	(3,849,729)	(2,040,374)
Loss from discontinued operations	<u>(71,966)</u>	<u>(119,643)</u>	<u>(402,077)</u>	<u>(221,496)</u>
Net loss	<u>(1,442,709)</u>	<u>(746,089)</u>	<u>(4,251,806)</u>	<u>(2,261,870)</u>
Less:				
Preferred stock deemed dividends	359,531	132,347	1,078,595	375,040
Preferred stock accretion	<u>323,247</u>	<u>12,614</u>	<u>969,743</u>	<u>37,842</u>
Net Loss Attributable to Common Stockholders	<u>\$ (2,125,487)</u>	<u>\$ (891,050)</u>	<u>\$ (6,300,144)</u>	<u>\$ (2,674,752)</u>
Net loss per share, basic and diluted:				
Continuing operations	(1.10)	(0.43)	(3.22)	(1.40)
Discontinued operations	<u>(0.04)</u>	<u>(0.07)</u>	<u>(0.22)</u>	<u>(0.13)</u>
Basic and diluted net loss per common share	<u>\$ (1.14)</u>	<u>\$ (0.50)</u>	<u>\$ (3.44)</u>	<u>\$ (1.53)</u>
Basic and diluted weighted average number of shares outstanding	<u>1,869,011</u>	<u>1,809,758</u>	<u>1,829,726</u>	<u>1,752,067</u>
Pro forma basic and diluted loss from continuing operations per common share	<u>\$ (0.21)</u>	<u>\$ (0.18)</u>	<u>\$ (0.59)</u>	<u>\$ (0.60)</u>
Pro forma basic and diluted weighted average number of common shares outstanding	<u>6,515,664</u>	<u>3,497,800</u>	<u>6,514,006</u>	<u>3,396,151</u>

See accompanying notes to financial statements

ELECTRO-OPTICAL SCIENCES, INC.

STATEMENTS OF CASH FLOWS
Nine Months Ended September 30,
(Unaudited)

	2005	2004
Cash flows from operating activities:		
Loss from continuing operations	\$ (3,849,729)	(2,040,374)
Loss from discontinued operations	(402,077)	(221,496)
Net loss	<u>\$ (4,251,806)</u>	<u>\$ (2,261,870)</u>
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for doubtful accounts	(1,000)	—
Depreciation and amortization	36,480	25,442
Noncash compensation and amortization of deferred compensation	94,695	16,875
Retirement of stock subscription receivable for consulting services	34,500	—
Amortization of discount on marketable securities	(33,502)	—
Imputed interest expense from bridge loan	—	80,000
Changes in operating assets and liabilities:		
Decrease (increase) in receivables	8,128	(6,209)
Increase in inventories	(16,122)	(9,312)
Decrease (increase) in prepaid expenses and other current assets	23,654	(685)
Deferred registration costs	(1,135,122)	(190,000)
Increase in accounts payable and accrued expenses	38,505	256,628
(Decrease) increase in deferred revenues	(106,335)	10,000
Decrease in other current liabilities	(6,408)	(8,736)
Net cash used in operating activities	<u>(5,314,333)</u>	<u>(2,087,867)</u>
Cash flows from investing activities:		
Patent costs	(2,822)	(3,167)
Purchases of property and equipment	(115,830)	(18,706)
Sale of marketable securities	6,628,253	—
Net cash provided by (used in) investing activities	<u>6,509,601</u>	<u>(21,873)</u>
Cash flows from financing activities:		
Proceeds from issuance of Series C preferred stock	—	1,100,000
Proceeds from issuance of notes payable	—	1,120,000
Proceeds from sale of common stock	7,300	137,500
Payment for stock subscription receivable	34,500	—
Net cash provided by financing activities	<u>41,800</u>	<u>2,357,500</u>
Net increase in cash and cash equivalents	1,237,068	247,760
Cash and cash equivalents at beginning of period	108,705	116,691
Cash and cash equivalents at end of period	<u>\$ 1,345,773</u>	<u>\$ 364,451</u>
Supplemental Schedule of Noncash Financing Activities:		
Preferred stock accretion	\$ 969,743	\$ 37,842
Accrued registration costs	\$ 701,488	—
Reclassification of inventories and patents to assets held for sale	\$ 156,677	—

See accompanying notes to financial statements

ELECTRO-OPTICAL SCIENCES, INC.
NOTES TO 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® a non-invasive, point-of-care instrument for assisting in the early diagnosis of melanoma. The Company has entered into a protocol agreement with the Food and Drug Administration (“FDA”) which is an agreement for the conduct of the pivotal trial and to establish the safety and effectiveness of the MelaFind® device. Upon obtaining premarket approval, or PMA, from the FDA, the Company plans to launch MelaFind® in the United States.

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

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 financial statements and notes thereto included in the Company’s registration statement on Form S-1, as amended (File No. 33-125517), which was declared effective by the Securities and Exchange Commission on October 28, 2005.

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. REVERSE STOCK SPLIT AND CONVERSION OF PREFERRED STOCK

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

In September 2005, the effective date of the automatic conversion of the Company’s designated preferred stock was changed to the date of completion of the Company’s initial public offering. Upon the completion of the Company’s initial public offering on October, 28, 2005, all of the Company’s redeemable convertible preferred stock was automatically converted into 3,398,105 shares of the Company’s common stock and all related deemed but unpaid dividends on the redeemable convertible preferred stock were forfeited.

3. MARKETABLE SECURITIES

Marketable securities consist of debt securities that the Company has the intent and ability to hold to maturity. The Company classifies the marketable securities as held-to-maturity in accordance SFAS No. 115, “Accounting for Certain Investments in Debt and Equity Securities.” Held-to-maturity securities are recorded at amortized cost. All marketable securities held to maturity were liquidated prior to September 30, 2005.

4. DEFERRED REGISTRATION COSTS

At September 30, 2005, the costs associated with the Company's initial public offering have been recorded as deferred registration costs. With the completion of the Company's initial public offering on October 28, 2005, these deferred registration costs will reduce additional paid-in capital.

5. 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. Actual results could differ from these estimates.

6. RECENT ACCOUNTING DEVELOPMENTS

On December 16, 2004 the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). This Statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements and establishes fair value as the measurement objective in accounting for all share-based payment arrangements. On March 29, 2005, the SEC issued Staff Accounting Bulletin No. 107, *Stock-Based Payment*, which summarizes the views of the staff regarding the interaction between SFAS 123R and certain SEC rules and regulations, and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS 123R was originally effective as of the beginning of the first interim or annual reporting period after June 15, 2005. However, on April 14, 2005 the SEC announced a new rule that amended the effective date for SFAS 123R. The new rule allows companies to implement SFAS 123R at the beginning of their next fiscal year, instead of the next reporting period beginning after June 15, 2005. As such, we will adopt SFAS 123R as of the beginning of the first quarter of 2006. The Company expects that upon the adoption of SFAS 123R it will apply the modified prospective application transition method, as permitted by the statement. Under such transition method, upon the adoption of SFAS 123R, the Company's financial statements for periods prior to the effective date of the statement will not be restated. The impact of this statement on the Company's financial statements or its results of operations will depend upon various factors, among them, its future compensation strategy. The Company expects that the effect of applying this statement on its results of operations as it relates to existing option plans could have a material effect on our financial statements.

7. STOCK-BASED COMPENSATION

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

The following table illustrates the effect on net loss attributable to common stockholders if the fair-value based method had been applied to all outstanding awards each period. The assumptions used to value the awards are included below. Because options granted vest over several years and additional awards are expected to be issued in the future, the pro forma results shown below are not likely to be representative of the effects on future years of the application of the fair-value based method.

[Table of Contents](#)**7. STOCK-BASED COMPENSATION (con't)**

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2005</u>	<u>2004</u>	<u>2005</u>	<u>2004</u>
Net loss attributable to common stockholders, as reported	\$ (2,125)	\$ (891)	\$ (6,300)	\$ (2,675)
Add: Stock-based employee compensation expense included in reported net loss	8	6	95	17
Deduct: Employee stock-based compensation expense under fair-value based method	(9)	(16)	(99)	(24)
Pro forma net loss attributable to common stockholders	<u>\$ (2,126)</u>	<u>\$ (901)</u>	<u>\$ (6,304)</u>	<u>\$ (2,682)</u>
Pro forma basic and diluted net loss per share of common stock	<u>\$ (1.14)</u>	<u>\$ (0.50)</u>	<u>\$ (3.45)</u>	<u>\$ (1.53)</u>
Basic and diluted net loss per share of common stock, as reported	<u>\$ (1.14)</u>	<u>\$ (0.50)</u>	<u>\$ (3.44)</u>	<u>\$ (1.53)</u>

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2005</u>	<u>2004</u>	<u>2005</u>	<u>2004</u>
Expected stock price volatility	—	60%	—	60%
Expected term until exercise	—	5 years	—	5 years
Risk-free interest rate	—	3.39%	—	3.39%
Expected dividend yield	—	0%	—	0%

8. DEFERRED COMPENSATION

Deferred compensation attributable to unvested common stock options is measured at the measurement date for the respective grants, and reflected as a deduction from stockholders' equity. Compensation expense is recognized ratably over the vesting period. The Company recognized \$24 and \$17 of amortization of deferred compensation as compensation expense for the nine months ended September 30, 2005 and 2004 respectively.

9. NET LOSS PER COMMON SHARE

Net loss per share is presented in accordance with the provisions of SFAS No. 128, *Earnings Per Share* (EPS). Basic EPS excludes dilution for potentially dilutive securities and is computed by dividing loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to dilutive options, warrants and other potential common shares outstanding during the period. Diluted net loss per common share is equal to basic net loss per common share since all potentially dilutive securities are anti-dilutive for each of the periods presented. Potential common stock equivalents consist of stock options, warrants and redeemable convertible preferred stock. The weighted average anti-dilutive shares for the three-month periods and nine-month periods ended September 30, 2005 and 2004 are summarized as follows:

9. NET LOSS PER COMMON SHARE (con't)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2005</u>	<u>2004</u>	<u>2005</u>	<u>2004</u>
Common stock options	895,674	407,182	919,035	394,793
Warrants	2,671,902	673,663	2,729,916	640,152
Redeemable convertible preferred stock	<u>3,398,105</u>	<u>1,387,853</u>	<u>3,398,105</u>	<u>1,345,728</u>
Total	<u>6,965,681</u>	<u>2,468,698</u>	<u>7,047,056</u>	<u>2,380,673</u>

10. PRO FORMA NET LOSS PER SHARE

Pro forma net loss per share is calculated using the weighted average number of shares of common stock outstanding, including the pro forma effects of the automatic conversion of all outstanding redeemable convertible preferred stock into shares of the Company's common stock effective upon the completion of the initial public offering, and the exchange of 2,610,643 warrants for 1,305,321 shares of common stock, using the as-if-converted method, as if such conversion or exchange had occurred as of January 1, 2004, or at the date of the original issuance, if later.

Upon the completion of the Company's initial public offering on October 28, 2005, all of the outstanding shares of redeemable convertible preferred stock were automatically converted into 3,398,105 shares of common stock. In addition, the loss from continuing operations used in the computation of unaudited pro forma basic and diluted loss from continuing operations per share has been adjusted to reverse the accretion on the Company's preferred stock and also excludes the preferred stock dividends for the respective periods.

11. COMMITMENTS AND CONTINGENCIES

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

During January 2004 the Company amended its employment agreement with its former President and Chief Science and Technology Officer. The agreement was originally entered into in May 2003 with a three-year term. The amended agreement included a salary of \$175 and provided for stock options and performance bonuses. As of May 31, 2005, a new consulting agreement was entered into with this former employee, which superceded the amended employment agreement (see Note 14).

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.

12. STOCKHOLDERS' (DEFICIENCY) EQUITY AND REDEEMABLE PREFERRED STOCK (AS RESTATED — SEE NOTE 16)

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

12. STOCKHOLDERS' (DEFICIENCY) EQUITY AND REDEEMABLE PREFERRED STOCK (AS RESTATED — SEE NOTE 16) (con't)

During February 2003, certain stockholders loaned the Company \$325 bearing interest at 12% per annum. In June 2003, these loans were converted into 143,802 shares of Series C redeemable convertible preferred stock at \$2.26 per share.

During June 2003, the Company completed a private placement whereby investors agreed to acquire up to 1,400,000 preferred Series C units. Each unit consists of one share of Series C redeemable convertible preferred stock and one warrant to purchase one share of common stock at an exercise price of \$13.00 per share. Of the 1,400,000 units, the first tranche of 663,717 units was sold for an aggregate of \$1,500. Costs associated with this issuance amounted to \$252 and the accretion to redemption value for this amount was \$38 for the nine months ended September 30, 2005. The value of the warrants was de minimus.

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

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

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

During May 2004, the Company obtained bridge loans in the amount of \$1,000 from related parties. The loans bear interest at 1.57% and were payable on December 31, 2004. During October 2004, these loans were converted into 442,469 preferred Series C units at a price of \$2.26 per unit. The warrants were valued at \$327. The Company also sold approximately 125,000 shares of common stock to the lenders at \$.46 per share for \$57. The Company ascribed a value to the common stock and recorded an imputed interest charge of \$80.

During October 2004, the Company completed a second private placement and sold 3,578,081 preferred Series C units for total proceeds of approximately \$8,100 at a price of \$2.26 per unit. The warrants were valued at \$2,653. Costs of the Series C private placement amounted to approximately \$448 and the accretion to redemption value for this amount was \$92 for the nine months ended September 30, 2005.

During 2004, the Company issued 4,507,702 shares of Series C redeemable convertible preferred stock with 2,253,792 warrants to purchase common stock at \$13.00 per share and 60,840 Series C redeemable convertible preferred stock warrants at an exercise price of \$4.52 per share for gross proceeds of \$10,186. The net proceeds of \$9,738 were allocated to redeemable convertible preferred stock and additional paid-in capital based on the relative fair values of the preferred stock and warrants. The fair value of the warrants was determined using the Black-Scholes method. The Company recorded a beneficial conversion feature of \$1,465. The accretion to redemption value for the value of the Series C warrants and the beneficial conversion feature for the nine months ended September 30, 2005 was \$541 and \$299 respectively.

12. STOCKHOLDERS' (DEFICIENCY) EQUITY AND REDEEMABLE PREFERRED STOCK (AS RESTATED — SEE NOTE 16) (con't)

The total accretion to redemption value for the Series C redeemable convertible preferred stock amounted to \$323, \$13, \$970 and \$38 for the three-month and nine-month periods ended September 30, 2005 and 2004, respectively.

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

Voting Rights

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

Liquidation Preference

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

Deemed Dividends

Dividends on the Series B and Series C redeemable convertible preferred stock may be declared at the discretion of the board of directors at an annual rate equal to 10%, as adjusted, of the accreted value per share and shall be payable in preference and priority to any declaration or payment of any distribution on Series A preferred stock or common stock and will be cumulative. At September 30, 2005 and December 31, 2004 there are approximately \$2,589 and \$1,510 of deemed but unpaid dividends. Upon the completion of the Company's initial public offering on October 28, 2005, all of the Company's preferred stock converted into common stock, and all related deemed dividends were forfeited.

Redemption Provisions

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

Upon the completion of the Company's initial public offering on October, 28, 2005, all of the Company's redeemable convertible preferred stock was automatically converted into 3,398,105 shares of the Company's common stock

Series C Preferred Stock Carrying Value

The following table summarizes the changes in carrying amount of the Company's Series C redeemable convertible preferred stock for the nine months ended September 30, 2005.

Balance at December 31, 2004	\$ 7,711
Preferred stock accretion	970
Balance at September 30, 2005	<u>\$ 8,681</u>

13. STOCK OPTIONS AND WARRANTS

Warrants

During the third quarter of 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, 2005 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 a 7 year warrant to purchase 73,280 shares of Series C preferred stock at an exercise price of \$4.52 per share issued in connection with the sale of Series C redeemable convertible preferred stock. Upon completion of the company's initial public offering on October 28, 2005, the Series C preferred stock warrants became exercisable for an aggregate of 73,280 shares of the company's common stock.

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

Stock Options

As of September 30, 2005, of the total 887,271 options outstanding, 445,596 will vest upon the attainment of certain milestones and their value will be charged to operations based on the then current market price per share of the Company's common stock.

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

14. RELATED PARTY CONSULTING AGREEMENTS:

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

Consulting Agreement with Breaux Castleman

In June 2003, the Company entered into a consulting agreement with Breaux Castleman, the Chairman of the Company's Board of Directors, for consulting services related to the FDA approval of MelaFind®, and the Company's business and financial strategy. Under this agreement, Mr. Castleman receives compensation for each month of services rendered. The Company made payments pursuant to this consulting agreement of \$48 in 2003, \$22 in 2004, and \$18 through September 30, 2005. This consulting agreement is terminable by either party on 30 days' written notice.

Consulting Agreement with Marek Elbaum, Ph.D.

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

14. RELATED PARTY CONSULTING AGREEMENTS (con't)

Consulting Agreement with Robert Friedman, M.D.

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

Consulting Agreement with Gerald Wagner, Ph.D.

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

15. DISCONTINUED OPERATIONS AND ASSETS HELD FOR SALE

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

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, 2005, assets held for sale consisted of DIFOTI® related inventories and patents.

In accordance with the provisions of SFAS No. 144, the results of operations of the discontinued business have been reported as discontinued operations for all periods presented in the accompanying financial statements. Losses attributable to DIFOTI® operations discontinued in April 2005 amounted to \$402 and \$221 for the nine months ended September 30, 2005 and 2004 respectively.

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16. REVISIONS TO PREVIOUSLY ISSUED FINANCIAL STATEMENTS AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2004.

The Company has recomputed the relative fair value of warrants and related beneficial conversion feature in connection with the issuance of Series C preferred stock in October 2004 referred to in Note 12. Such recomputation resulted in a change in the preferred stock accretion for the year ended December 31, 2004. The following table summarizes the recomputation of the fair values.

	<u>As previously reported</u>	<u>As restated</u>	<u>Adjustment</u>
Value of warrants	\$ 3,159	\$ 2,643	\$ 516
Value of beneficial conversion feature	2,385	1,465	920

A summary of the changes to the Company's previously issued financial statements for the year ended December 31, 2004 is as follows:

	<u>Series C preferred stock</u>	<u>Additional paid-in capital</u>	<u>Stockholders' (deficiency) equity</u>
As previously reported, December 31, 2004	\$ 6,341	\$ 10,981	\$ (2,180)
Adjustment of relative fair value of warrants issued with Series C preferred stock	516	(516)	(516)
Adjustment of amount of beneficial conversion feature	920	(920)	(920)
	1,436	(1,436)	(1,436)
Adjustment of accretion applicable to Series C preferred stock	(66)	66	66
As restated, December 31, 2004	<u>\$ 7,711</u>	<u>\$ 9,611</u>	<u>\$ (3,550)</u>

Net loss attributable to common stockholders for the year ended December 31, 2004 was reduced as follows as a result of reductions in preferred stock accretion:

	<u>Year ended December 31, 2004</u>	
	<u>Total</u>	<u>Per Common Share</u>
As previously reported	\$ (4,619)	\$ (2.61)
Reduction in accretion applicable to preferred stock	66	(.03)
As restated	<u>\$ (4,553)</u>	<u>\$ (2.58)</u>

17. SUBSEQUENT EVENT

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 \$17,740. 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. Because the offering closed after September 30, 2005, the results of the offering are not reflected in the accompanying unaudited financial statements. A summary of the terms of the initial public offering can be found in the Company's registration statement on Form S-1, as amended (File No. 33-125517), which was declared effective by the Securities and Exchange Commission on October 28, 2005.

The following table presents summary balance sheet information as of September 30, 2005 to give effect on a pro forma basis to the sale of 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, and the automatic conversion of all outstanding shares of the Company's convertible preferred stock into 3,398,105 shares of common stock upon completion of the Company's initial public offering:

	As of September 30, 2005	
	Actual	Pro forma
Total current assets	\$ 3,345	\$ 20,383
Total noncurrent assets	298	298
Total assets	\$ 3,643	\$ 20,681
Total current liabilities	\$ 1,318	\$ 616
Series B & C Redeemable convertible preferred stock	10,925	—
Stockholders (deficiency)/equity:		
Series A preferred stock	973	—
Common stock	2	11
Additional paid-in capital	8,719	38,348
Deferred compensation	(135)	(135)
Accumulated deficit	(18,159)	(18,159)
Total stockholders' (deficiency) equity	(8,600)	20,065
Total liabilities and stockholders' (deficiency) equity	\$ 3,643	\$ 20,681

ITEM 2.

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

This management's discussion and analysis of financial condition and results of operations is intended to provide information to help you better understand and evaluate our financial condition and results of operations. We recommend that you read this section in conjunction with our Financial Statements and Notes to Financial Statements in Item 1 and with our Registration Statement on Form S-1, as amended (File No. 33-125517), which was declared effective by the Securities and Exchange Commission on October 28, 2005.

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

Overview

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

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

We commenced operations in December 1989 as a New York corporation and re-incorporated as a Delaware corporation in September 1997. Since our inception, we have generated significant losses. As of September 30, 2005, we had an accumulated deficit of \$18.2 million. We expect to continue to spend significant amounts on the development of MelaFind®. We expect to incur significant commercialization costs when we begin to introduce MelaFind® into the US market. On October 28, 2005, 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® and generate revenues.

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

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

General and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with our efforts to obtain PMA approval for MelaFind® and toward development of a commercial infrastructure to market and sell MelaFind®. We anticipate that general and administrative expenses will increase as a result of the expected expansion of our operations, facilities and other activities associated with the planned expansion of our business, together with the additional costs associated with operating as a public company. We expect selling, general and administrative expenses to increase as we develop our sales and marketing capabilities to support placing MelaFind® 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® product effective as of April 5, 2005, and account for the DIFOTI® revenue and expenses as a discontinued operation. Revenue from the DIFOTI® product sales had been recognized at the time of delivery and acceptance, after consideration of all the terms and conditions of the customer contract. The DIFOTI® products which were being sold prior to December 31, 2004 included a 30-day return policy. Revenue on these products was recognized after the shipment was made and the 30-day return period had elapsed. DIFOTI® products sold subsequent to December 31, 2004 were sold without a right of return and revenue was therefore recognized after the shipment was made. Deferred revenues at December 31, 2004 consisted of revenues that were billed or paid in advance of the shipment of the product.

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

Stock-Based Compensation

We account for stock-based compensation to employees under the intrinsic-value-based method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and disclose the effect of the differences which would result had we applied the fair-value-based method of accounting, on a pro forma basis, as required by FASB Statement No. 123, "Accounting for Stock-Based Compensation, as amended by Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for

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Stock-Based Compensation, Transition and Disclosure.” In December 2004, FASB issued FASB Statement No. 123R, which addresses the accounting for share-based awards to employees and requires companies to recognize the fair value of stock options and other stock-based compensation to employees in their statement of operations. Because we currently account for our stock-based compensation plans in accordance with APB Opinion No. 25, the adoption of FASB Statement No. 123R could have a material effect on our financial statements in future accounting periods.

At September 30, 2005, our common stock was not publicly traded and the determination of the fair value of our common stock involved considerable judgment. In making this determination, we evaluated, among other things, our common stock transactions, the pricing of private equity sales, the rights and preferences of the security being valued, current market conditions, and company specific operational milestones.

We have granted to certain employees stock options that vest with the attainment of various performance milestones. Upon the attainment of these milestones we will be required to recognize a stock based compensation expense in an amount based on the then current fair market value of our common stock underlying the options which vest when the milestone is attained. In May 2005, we amended option agreements for 125,000 shares in the aggregate of three key employees to immediately vest upon the completion of a successful initial public offering. We will record in the fourth quarter of 2005 a charge to operations in the amount of \$544 with respect to these options based upon the initial public offering price of \$5.00 per share. We have also granted options that vest upon attainment of development milestones. Upon the attainment of each of the relevant development milestones assuming the initial public offering price remains the fair market value per share of our common stock, and that the number of shares of our common stock outstanding after this initial public offering, including the exercise of a portion of the over-allotment by the underwriters, remains 10,785,464, we will record a compensation expense: (1) upon filing our MelaFind® PMA with the FDA of \$227,000 with respect to 50,000 shares underlying options with an exercise price of \$0.46 per share; and (2) upon our receipt of PMA approval for MelaFind® of \$228,000 with respect to 50,000 shares underlying options with a weighted average exercise price of \$0.44 per share and of \$1,836,162 with respect to 404,441 shares underlying options with an exercise price of \$0.46 per share.

Accrued Expenses

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

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

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

Results of Operations (in thousands)

Three Months Ended September 30, 2005 Compared to Three Months Ended September 30, 2004

Research and Development Expense. Research and development expense for the three months ended September 30, 2005 was \$876, as compared with \$423 for the three months ended September 30, 2004. This increase was attributable to higher personnel and personnel related costs of \$50, as we increased headcount to support our research and development programs, and \$371 related to increased consulting and outside research fees for the development of our MelaFind® product.

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General and Administrative Expense. General and administrative expense for the three months ended September 30, 2005 was \$492 as compared with \$204 for the three months ended September 30, 2004. The increase is due to increased legal and consulting fees of \$133, higher personnel and personnel related costs of \$30 associated with the addition of key management positions, \$35 related to rent and moving expenses for the additional office space, information technology consulting and general office related expenses of \$64.

Interest (Income)/Expense. Interest (income)/expense for the three months ended September 30, 2005 was \$3.

Nine Months Ended September 30, 2005 Compared to Nine Months Ended September 30, 2004

Research and Development Expense. Research and development expense increased by \$1,306 to \$2,422 for the nine months ended September 30, 2005 from \$1,116 for the nine months ended September 30, 2004. Of this increase, \$461 was attributable to higher personnel and personnel related costs as we increased headcount to support our research and development programs, and \$769 related to increased consulting and outside research fees for the development of our MelaFind® product.

General and Administrative Expense. General and administrative expense increased by \$645 to \$1,488 for the nine months ended September 30, 2005 from \$843 for the nine months ended September 30, 2004. The change was due to higher personnel and personnel related costs of \$170 associated with the addition of key management positions, \$79 related to rent and moving expenses for the additional office space, share-based compensation expense of \$78, information technology consulting and general office related expenses of \$140.

Interest (Income)/Expense. Interest (income)/expense for the nine months ended September 30, 2005 was (\$60) compared to \$82 for the corresponding period in 2004. The increase in income for the nine months ended September 30, 2005 was due to the higher average cash, cash equivalents and marketable securities balance compared to the prior year period. The interest expense for the nine months ended September 30, 2004 principally related to an imputed interest charge of \$80 in connection with financings from related parties.

Liquidity and Capital Resources (in thousands)

From inception, we have financed our operations primarily through the use of working capital from private placements of equity securities and by applying for and obtaining a series of National Institute of Health Small Business Innovative Research grants and similar grants. To date, we have not borrowed (other than by issuing convertible notes, all of which have been converted into equity) or financed our operations through significant financing loans or other debt instruments. As of September 30, 2005, we had \$1,346 in cash, cash equivalents and marketable securities as compared to \$6,703 at December 31, 2004. Our cash, cash equivalents and marketable securities are liquid investments with a maturity within one year and consist of investments in money market funds with a commercial bank and short-term US Treasury obligations and federal agency notes.

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.

Cash Flows from Operating Activities. Net cash used in operations was \$5,314 for the nine months ended September 30, 2005. For the corresponding period in 2004, net cash used in operations was \$2,088. Cash used in operations was attributable to net losses after an adjustment for non-cash charges related to depreciation and other changes in operating assets and liabilities.

Cash Flows from Investing Activities. Net cash provided by our investing activities was \$6,510 for the nine months ended September 30, 2005 principally related to the redemption of investments. For the corresponding period in 2004, net cash used in investing activities was \$22.

Cash Flows from Financing Activities. Net cash provided by financing activities was \$42 for the nine months ended September 30, 2005. For the corresponding period in 2004, net cash flows provided by financing activities was \$2,358. For these periods, financing cash flows reflected the proceeds from the issuance of common stock, as well as preferred stock and notes payable in 2004.

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We face certain risks and uncertainties, which are present in many emerging medical device companies. At September 30, 2005, we had an accumulated deficit of \$18.2 million and anticipate that we will continue to incur net losses for the foreseeable future in the development and commercialization of the MelaFind® device.

Operating Capital and Capital Expenditure Requirements

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

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

- the schedule, costs and results of our clinical trials;
- the success of our research and development efforts;
- the costs and timing of regulatory approval;
- 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 cost and the results of such litigation;
- the cost 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, 2005 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

Contractual Obligations

	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u> (dollars in thousands)	<u>4-5 years</u>	<u>More than 5 years</u>
Operating Leases	\$ 952	\$ 205	\$ 608	\$ 139	—
Total	<u>\$ 952</u>	<u>\$ 205</u>	<u>\$ 608</u>	<u>\$ 139</u>	<u>\$ —</u>

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.

Related Party Transactions

For a description of our related party transactions, see our financial statements and the related notes to our financial statements in Item 1.

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.

Risk factors

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

Risks Relating to Our Business

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

We currently do not have any commercialized products or any significant source of revenue. We have invested substantially all of our time and resources over the last five years in developing MelaFind®. MelaFind® will require additional development, clinical evaluation, regulatory approval, significant marketing efforts and substantial additional investment before it can provide us with any revenue. Our efforts may not lead to commercially successful products for a number of reasons, including:

- we may not be able to obtain regulatory approvals for MelaFind®, or the approved indication may be narrower than we seek;
- MelaFind® may not prove to be safe and effective in clinical trials;
- physicians may not receive any reimbursement from third-party payors, or the level of reimbursement may be insufficient to support widespread adoption of MelaFind®;
- we may experience delays in our development program;
- any products that are approved may not be accepted in the marketplace by physicians or patients;
- we may not have adequate financial or other resources to complete the development or to commence the commercialization of MelaFind® and will not have adequate financial or other resources to achieve significant commercialization of MelaFind®;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost; and
- rapid technological change may make our technology and products obsolete.

We do not expect to be able to commercialize MelaFind® before 2007. If we are unable to develop, obtain regulatory approval for or successfully commercialize MelaFind®, we will be unable to generate revenue.

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

We do not have the necessary regulatory approvals to market MelaFind® in the US or in any foreign market. We have not filed, and currently do not have plans to file, for regulatory approval in any foreign market. We plan initially to launch MelaFind®, once approved, in the US. The regulatory approval process for MelaFind® in the US involves, among other things, successfully completing clinical trials and obtaining PMA approval from the FDA. We commenced the PMA application process for MelaFind® by filing a proposed outline for a Modular PMA application (a compilation of well-delineated components submitted separately) on September 30, 2002. The PMA process requires us to prove the safety and effectiveness of MelaFind® to the FDA's satisfaction. This process is expensive and uncertain, and requires detailed and comprehensive scientific and human clinical data. FDA review may take years after a PMA application is filed. The FDA may never grant approval. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- MelaFind® may not be safe or effective to the FDA's satisfaction;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;

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- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

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

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

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

If we wish to modify MelaFind® after receiving FDA approval, including changes in indications or other modifications that could affect safety and effectiveness, additional approvals could be required from the FDA. We may be required to submit extensive pre-clinical and clinical data, depending on the nature of the changes. Any request by the FDA for additional data, or any requirement by the FDA that we conduct additional clinical studies, could delay the commercialization of MelaFind® and require us to make substantial additional research, development and other expenditures. We may not obtain the necessary regulatory approvals to market MelaFind® in the US or anywhere else. Any delay in, or failure to receive or maintain, approval for MelaFind® could prevent us from generating revenue or achieving profitability, and our business, financial condition, and results of operations would be materially adversely affected.

MelaFind® may not be commercially viable if we fail to obtain an adequate level of reimbursement by Medicare and other third party payors. The markets for MelaFind® may also be limited by the indications for which its use may be reimbursed.

The availability of medical insurance coverage and reimbursement for newly approved medical devices is uncertain. In the US, physicians and other healthcare providers performing biopsies for suspicious skin lesions are generally reimbursed for all or part of the cost of the diagnosis and biopsy by Medicare, Medicaid, or other third-party payors.

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

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

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, according to an industry report, Medicare coverage determinations for medical devices lag 15 months to five years or more behind FDA approval for that device. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state by state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the US Department of Health and Human Services (HHS). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations.

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

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

Risk of delay in product development.

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

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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 258 melanoma lesions are in the training database. The current classifier has been trained on 113 of these melanoma lesions. Our schedule for the acquisition of these lesions is based upon the projected numbers of imaging devices to be located at participating sites, the projected productivity of those sites in terms of melanomas and other lesions biopsied per month, and the projected efficiency of the study pathologists in classifying the lesion slides presented for histological analysis (the microscopic examination of excised or biopsied tissue specimens) and reporting their results. If we are unable to produce and maintain a sufficient number of imaging devices at participating sites, if the clinicians do not maintain sufficient productivity, or if the pathologists do not produce reports with sufficient efficiency, then our ability to maintain our schedule will be adversely affected, the start or conclusion of the pivotal trial may be delayed, and the submission of the completed PMA will be delayed.

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

We have incurred losses for a number of years, and anticipate that we will incur continued losses for the foreseeable future.

We began operations in December 1989. At that time we provided research services, mostly to US government agencies, on classified projects. We have financed our operations since 1999 primarily through private placements of our equity securities, and have devoted substantially all of our resources to research and development relating to MelaFind®. Our net loss for the nine months ended September 30, 2005 was \$4.3 million, and as of September 30, 2005, we had an accumulated deficit of approximately \$18.2 million. We expect our research and development expenses to increase in connection with our clinical trials and other development activities related to MelaFind®. If we receive PMA approval for MelaFind® from the FDA, we expect to incur significant sales and marketing expenses, which will require additional funding, and manufacturing expenses. Additionally, we expect that our general and administrative expenses will increase due to the additional operational and regulatory responsibilities applicable to public companies. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

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

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;

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- additional lines of products, and the ability to offer rebates, higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

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

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

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

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

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

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

- the FDA, an Institutional Review Board (IRB), or other regulatory authorities place our clinical trial on hold;

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

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

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

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

MelaFind® may never achieve market acceptance even if we obtain regulatory approvals.

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

- perceived effectiveness of MelaFind®;
- convenience of use;
- cost of the use of MelaFind®;
- availability and adequacy of third-party coverage or reimbursement;

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- approved indications and product labeling;
- publicity concerning MelaFind® or competitive products;
- potential advantages over alternative diagnostic methodologies;
- introduction and acceptance of competing products or technologies; and
- extent and success of our sales, marketing and distribution efforts.

The identification and screening of melanomas is now dominated by visual clinical evaluation, with a minority of dermatologists using dermoscopy. Even if MelaFind® proves to be as effective as visual inspection by an expert dermatologist, and if all approvals are obtained, the success of MelaFind® will depend upon the acceptance by dermatologists and other physicians who perform skin examinations and treat skin disorders, including industry opinion leaders, that the diagnostic information provided by MelaFind® is medically useful and reliable. We will be subject to intense scrutiny before physicians will be comfortable incorporating MelaFind® in their diagnostic approaches. We believe that recommendations by respected physicians will be essential for the development and successful marketing of MelaFind®, and there can be no assurance that any such recommendations will be obtained. To date, the medical community outside the limited circle of certain dermatologists specializing in melanoma has had little exposure to us and MelaFind®. Because the medical community is often skeptical of new companies and new technologies, we may be unable to gain access to potential customers in order to demonstrate the operation and effectiveness of MelaFind®. Even if we gain access to potential customers, no assurance can be given that members of the dermatological, or later the general practice, medical community will perceive a need for or accept MelaFind®. In particular, given the potentially fatal consequences of failing to detect melanoma at the early, curable stages, practitioners may remain reluctant to rely upon MelaFind® even after we receive approval from the FDA for marketing the product.

Any of the foregoing factors, or other currently unforeseen factors, could limit or detract from market acceptance of MelaFind®. Insufficient market acceptance of MelaFind® would have a material adverse effect on our business, financial condition and results of operations.

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

Our operations have consumed substantial amounts of cash for each of the last six years. We currently believe that our available cash, cash equivalents and marketable securities, together with the proceeds from our recently completed initial public offering, will be sufficient to fund our anticipated levels of operations through mid 2007. However, our business or operations may change in a manner that would consume available resources more rapidly than we anticipate. We expect to continue to spend substantial amounts on research and development, including conducting a clinical trial for MelaFind®. We will need additional funds to fully commercialize the product, including development of a direct sales force and expansion of manufacturing capacity. We expect that our cash used by operations will increase significantly in each of the next several years, and should we encounter any material delays or impediments, we may need additional funds to complete the development of MelaFind® and commence commercialization of MelaFind® and we will need additional funds to achieve significant commercialization of MelaFind®. Any additional financing may be dilutive to stockholders, or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

- the schedule, costs, and results of our clinical trials;
- the success of our research and development efforts;
- the costs and timing of regulatory approval;
- reimbursement amounts for the use of MelaFind® that we are able to obtain from Medicare and third party payors, or the amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind®;
- the cost of commercialization activities, including product marketing and building a domestic direct sales force;

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- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other rights, including litigation costs and the results of such litigation;
- the costs involved in defending any patent infringement actions brought against us by third parties; and
- our ability to establish and maintain any collaborative, licensing or other arrangements, and the terms and timing of any such arrangements.

Additional financing may not be available to us when we need it, or it may not be available on favorable terms. If we are unable to obtain adequate financing on a timely basis, we may be required to significantly curtail or cease one or more of our development and marketing programs. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise pursue on our own. We also may have to reduce marketing, customer support and other resources devoted to our products. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience ownership dilution, could experience declines in our share price and the terms of any new equity securities may have preferences over our common stock.

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

We do not have a sales organization, and have no experience as a company in the marketing and distribution of devices such as MelaFind®. To achieve commercial success for MelaFind®, we must develop a sales and marketing force and enter into arrangements with others to market and sell our products. Following product approval, we currently plan to establish a small direct sales force to market MelaFind® in the US, focused on introducing it at high volume dermatologists' offices and training their staff in its use, but we have not made any final determinations regarding the use of a particular marketing channel. We anticipate that we will need additional funds in order to implement this marketing plan. In addition to being expensive, developing such a sales force is time consuming, and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. Qualified direct sales personnel with experience in the medical device market are in high demand, and there is no assurance that we will be able to hire or retain an effective direct sales team. Similarly, qualified, independent medical device representatives both within and outside the US are in high demand, and we may not be able to build an effective network for the distribution of our product through such representatives. We have no assurance that we will be able to enter into contracts with representatives on terms acceptable or reasonable to us. Similarly, there is no assurance that we will be able to build an alternate distribution framework, should we attempt to do so.

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

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

We have not yet completed the development and testing of MelaFind®, and as a result have no experience in manufacturing MelaFind® for commercial distribution. We currently have limited resources, facilities and experience to commercially manufacture MelaFind®. In order to produce MelaFind® in the quantities we anticipate to meet market demand, we will need to increase our third-party manufacturing capacity. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, material procurement, problems with production yields, and quality control and assurance. Developing commercial-scale manufacturing facilities that meet FDA requirements would require the investment of substantial additional funds and the hiring and retaining of additional management and technical personnel who have the necessary manufacturing experience.

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

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

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

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

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

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

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

We have entered into a development agreement with ASKION GmbH (ASKION) to complete developmental engineering and testing of our hand-held imaging device, and have entered into a non-binding Letter of Intent with ASKION to assemble the components and produce initial quantities of our hand-held imaging devices for clinical trials. We intend to enter into a contract for commercial production of the hand-held imaging devices once specifications for MelaFind® have been finalized, but we may not be able to enter such an agreement on mutually acceptable terms. Failure to enter into such an agreement with ASKION would require us to expand our own manufacturing facilities or obtain such services elsewhere. Similarly, we have entered into a confidentiality agreement and a development agreement with Carl Zeiss Jena GmbH for lens objective assemblies, and we intend to enter into a contract for the commercial production of lenses. These lenses are currently assembled by ASKION utilizing the lens elements produced by Optyka. The manufacturing agreement with ASKION will include integration of these lenses in the hand-held imaging devices. Our planned reliance upon an outside provider for assembly and production services subjects us to the risk of adverse consequences from delays and defects caused by the failure of such outside supplier to meet its contractual obligations, including confidentiality obligations in the case of Carl Zeiss Jena GmbH, which is an affiliate of Carl Zeiss AG, a potential competitor. The failure by us or our supplier to produce a sufficient number of hand-held imaging devices that can operate according to our specifications could delay the pivotal clinical trial and/or the commercial sale of MelaFind®, and would adversely affect both our ability to successfully commercialize MelaFind® and our business, financial condition and results of operations.

We will not be able to sell MelaFind® unless and until its design is verified and validated in accordance with current good manufacturing practices as set forth in the US medical device Quality System Regulation.

We are in the process, but have not yet successfully completed, all the steps necessary to verify and validate the design of the MelaFind® system that are required to be performed prior to commercialization. If we are delayed or unable to complete verification and validation successfully, we will not be able to sell MelaFind®, and we will not be able to meet our plans for the commercialization of MelaFind® in 2007.

Assuming that regulatory approval of MelaFind® is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or effectiveness of the device. Later discovery of previously unknown problems with MelaFind®, including manufacturing problems, or failure to comply with regulatory requirements such as the Quality System Regulation (a set of current good manufacturing practice requirements put forth by the FDA which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation and servicing of finished devices) (QSR), may result in restrictions on MelaFind® or its manufacturing processes, withdrawal of MelaFind® from the market, patient or physician notification, voluntary or mandatory recalls, fines, withdrawal of regulatory approvals, refusal to approve pending applications or supplements to approved applications, refusal to permit the import or export of our products, product seizures, injunctions or the imposition of civil or criminal penalties. Should any of these enforcement actions occur, our business, financial condition and results of operations could be materially and adversely affected.

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continuous review and periodic inspections by the FDA and other regulatory bodies. In particular, we and our suppliers are required to comply with the QSR and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, promotion, distribution, and shipping of MelaFind®, and with record keeping practices. We also will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports and registration and listing requirements. To the extent that we contract with third parties to manufacture some of our products, our manufacturers will be required to adhere to current Good Manufacturing Practices (cGMP) requirements enforced by the FDA as part of QSR, or similar regulations required by regulatory agencies in other countries. The manufacturing facilities of our

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contract manufacturers must be inspected or must have been inspected, and must be in full compliance with cGMP requirements before approval for marketing. The FDA enforces the QSR and other regulatory requirements through unannounced inspections. We have not yet been inspected by the FDA for MelaFind®, and will have to complete such an inspection successfully before we ship any commercial MelaFind® devices. However, we were previously inspected in connection with DIFOTI®, which we have discontinued for business reasons, and were cited for failures to comply fully with QSR mandated procedures. The FDA inspectors observed deficiencies that were documented on FDA Form 483 that was issued to us following the inspection. We have discussed the findings in a subsequent meeting with the FDA and are in the process of addressing the deficiencies. We are working with consultants to address the inspectional findings, particularly as they relate to current MelaFind® design development and ultimate MelaFind® commercial manufacturing. If we are not successful in convincing the FDA that we are capable of addressing its concerns, or if our efforts to address the deficiencies should prove unsuccessful, we might be subject to additional FDA action of a type described below, which could negatively affect our ability to commercialize MelaFind®.

There can be no assurance that the future interpretations of legal requirements made by the FDA or other regulatory bodies with possible retroactive effect, or the adoption of new requirements or policies, will not adversely affect us. We may be slow to adapt, or may not be able to adapt to these changes or new requirements. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions:

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

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

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

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

The federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Food, Drug, and Cosmetic Act (FD&C Act), as well as other relevant laws; (ii) CMS, which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General (OIG) which enforces various laws aimed at curtailing fraudulent or abusive practices, including by way of example, the Anti-Kickback Law, the Anti-Physician Referral Law, commonly referred to as Stark, the Anti-

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Inducement Law, the Civil Money Penalty Law, and the laws that authorize the OIG to exclude healthcare providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights, which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All of the aforementioned are agencies within HHS. Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Public Health Service within HHS under the Public Health Service Act, the Department of Justice through the Federal False Claims Act and various criminal statutes, and state governments under Medicaid and other state sponsored or funded programs and their internal laws regulating all healthcare activities.

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

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

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

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

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

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

The application of the privacy provisions of HIPAA is uncertain.

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

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

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

Any infringement or misappropriation claim could cause us to incur significant costs, could place significant strain on our financial resources, divert management’s attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign MelaFind® to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing MelaFind®, and/or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

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

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

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

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There can be no assurance that we will be successful in entering into such licensing arrangements on terms favorable to us or at all. Failure to develop, obtain necessary regulatory clearances or approvals for, or successfully market potential new products could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

We may be adversely affected by a data center failure.

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

We may be adversely affected by breaches of online security.

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

We are dependent upon telecommunications and the internet.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have granted to certain employees stock options that vest with the attainment of various performance milestones. Upon the attainment of these milestones we will be required to recognize a stock based compensation expense in an amount based on the then current fair market value of our common stock underlying the options which vest when the milestone is attained. In May 2005, we amended option agreements for 125,000 shares in the aggregate of three key employees to immediately vest upon the completion of a successful initial public offering. We will record in the fourth quarter of 2005 a charge to operations in the amount of \$544 with respect to these options based upon the initial public offering price of \$5.00 per share. We have also granted options that vest upon attainment of development milestones. Upon the attainment of each of the relevant development milestones assuming the initial public offering price remains the fair market value per share of our common stock, and that the number of shares of our common stock outstanding after this initial public offering, including the exercise of a portion of the over-allotment by the underwriters, remains 10,785,464, we will record a compensation expense: (1) upon filing our MelaFind® PMA with the FDA of \$227,000 with respect to 50,000 shares underlying options with an exercise price of \$0.46 per share; and (2) upon our receipt of PMA approval for MelaFind® of \$228,000 with respect to 50,000 shares underlying options with a weighted average exercise price of \$0.44 per share and of \$1,836,162 with respect to 404,441 shares underlying options with an exercise price of \$0.46 per share.

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

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

Risks Relating to our Common Stock

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

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

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

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

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

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

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

As of October 28, 2005, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates will, in the aggregate, beneficially own approximately 28% of our outstanding common stock. 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

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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 October 28, 2005, we have 10,523,164 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. Taking into consideration the effect of lock-up agreements that have been entered into by certain of our stockholders, we estimate that 6,523,164 shares of our common stock outstanding will be available for sale pursuant to Rule 144 and Rule 144(k), as follows:

- beginning on October 28, 2005, in addition to the 4,000,000 shares sold in our initial public offering, approximately 1,229,577 of our restricted shares will be eligible for sale under Rule 144, of which approximately 408,402 shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144 and approximately 821,175 shares will be eligible for sale as unrestricted shares under Rule 144(k);
- beginning 270 days after October 28, 2005, approximately 6,347,015 of our restricted shares will be eligible for sale under Rule 144 (which includes the 1,229,577 restricted shares referred to above), of which approximately 3,226,819 shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144 and approximately 3,120,196 shares will be eligible for sale as unrestricted shares under Rule 144(k); and
- beginning October 27, 2006, approximately an additional 176,149 of our restricted shares will be eligible for sale subject to the volume, manner of sale and other limitations under Rule 144.

Within nine months following October 28, 2005, we intend to register up to 1,899,875 shares of common stock that are authorized for issuance under our stock option plans. As of September 30, 2005, 887,271 shares were subject to outstanding options, of which 434,175 shares were vested. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above and restrictions on our affiliates.

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

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

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

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

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

Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

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

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. While the outcome of these legal proceedings cannot be predicted with certainty, we do not expect that these proceedings will have a material effect upon our financial condition or results of operations.

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

(a) Upon completion of our initial public offering, we issued a warrant to purchase up to an aggregate of 75,000 shares of our common stock to ThinkEquity Partners LLC and a warrant to purchase up to an aggregate of 75,000 shares of our common stock to Stanford Group Company as co-managing underwriters for our initial public offering. The warrants are not exercisable until October 28, 2006, the first anniversary of the date of our prospectus. Thereafter, the warrants are exercisable at an exercise price equal to 125% of the public offering price per share of \$5.00. The period within which the warrants are exercisable ends on October 28, 2010, the fifth anniversary of the date of our final prospectus.

The warrants issued to the underwriters include a “cashless” exercise provision entitling the holder to convert the warrant into shares of our common stock. The warrants may not be sold, transferred, assigned or hypothecated for a period of one year from the date of our final prospectus, except to officers or partners of the underwriters and members of the selling group and/or their officers or partners.

(b) On October 28, 2005, the SEC declared effective our Registration Statement on Form S-1 (File No. 333-125517) in connection with our initial public offering. The offering commenced as of October 28, 2005. The co-managing underwriters of the offering were ThinkEquity Partners LLC and Stanford Group Company. The offering did not terminate before any securities were sold, but as of the date of the filing of this report, the offering has terminated and 4,000,000 shares of our common stock registered were sold (excluding shares sold pursuant to the underwriters over-allotment option discussed below).

All 4,000,000 shares of our common stock registered in the offering were sold at the initial public offering price per share of \$5.00. The aggregate purchase price of the offering was \$20 million. We incurred total estimated expenses, including the underwriters’ discount and commissions in connection with the offering, of approximately \$3.5 million. No payments for such expenses were made directly or indirectly to any of our directors, officers or their associates, any person(s) owning 10% or more of any class of our equity securities, or any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service. Thus, the net offering proceeds to us after deducting total expenses were approximately \$16.5 million.

On November 15, 2005, the underwriters for our initial public offering exercised their over-allotment option and purchased an additional 262,300 shares of common stock at a price of \$5.00 per share. The proceeds from the exercise of the over-allotment option were \$1,219,695, after deducting \$91,805 for underwriting discounts and commissions.

The net offering proceeds have been temporarily placed in an interest-bearing sweep account. We are currently in the process of deciding where and in what to invest the proceeds.

We have begun to use, and intend to continue to use, these proceeds for research and development activities including clinical trials, development of our sales and marketing capabilities and general corporate purposes including general and administrative expenses, as described in the use of proceeds section of our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 28, 2005.

Item 3. Defaults Upon Senior Securities.

Not applicable.

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

On September 22, 2005, we sent a letter to our security holders requesting acknowledgement of the change in underwriters for our initial public offering and confirming that the consents and waivers obtained pursuant to a previous letter dated June 10, 2005 remained valid. Pursuant to such letter, all security holders who had previously executed a lock-up agreement with Ladenburg Thalmann & Co. Inc. also consented to an identical lock-up agreement with ThinkEquity Partners, LLC, which replaced Ladenburg as one of the co-managing underwriters in our initial public offering.

The number of consents received for, and the number not received, is as follows:

	<u>For</u>	<u>Not Received</u>
1. Series A Preferred Stock holders	195,497	34,908
2. Series B Preferred Stock holders	863,144	287,928
3. Series C Preferred Stock holders	5,076,221	338,558
4. Common Stock holders	<u>3,540,991</u>	<u>78,525</u>
TOTAL	9,675,853	739,919

Item 5. Other Information.

(a) Not applicable.

(b) Not applicable.

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ITEM 6. Exhibits

- 3.1 Fourth Amended and Restated Certificate of Incorporation. *
- 3.2 By-laws. **
- 4.1 Specimen Common Stock Certificate. **
- 4.2 Specimen Warrant Certificate (incorporated by reference from Exhibit 4.3). ***
- 4.3 Form of Warrant Agreement entered into by and between the Registrant, ThinkEquity Partners LLC and Stanford Group Company. ***
- 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 Principal 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.

* 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.

** 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.

*** 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.

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

Date: December 2, 2005

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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 Principal 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

**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)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operations of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 2, 2005

/s/ Joseph V. Gulfo

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

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

I, Karen Krumeich, certify that:

1. I have reviewed this report on Form 10-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)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operations of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 2, 2005

/s/ Karen Krumeich

Karen Krumeich
Vice President & 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, 2005 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo

JOSEPH V. GULFO

President and Chief Executive Officer

(Principal Executive Officer)

December 2, 2005

/s/ Karen Krumeich

KAREN KRUMEICH

Vice President & Chief Financial Officer

(Principal Accounting and Financial Officer)

December 2, 2005

*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.