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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, 2010

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000 — 51481

**MELA 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.)*

**50 South Buckhout Street, Suite 1  
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 a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer" "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

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 1, 2010: 25,253,136 shares of the Registrant's common stock were outstanding.

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**MELA SCIENCES, INC.**  
**CONDENSED BALANCE SHEETS**

	<u>September 30,</u> <u>2010</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2009</u> <u>*</u>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 35,755,664	\$ 29,673,420
Prepaid expenses and other current assets	393,156	664,962
<b>Total Current Assets</b>	<b>36,148,820</b>	<b>30,338,382</b>
Property and equipment, net	2,235,365	1,571,956
Patents and trademarks, net	74,083	83,008
Deferred financing costs	62,391	85,570
Other assets	337,705	48,000
<b>Total Assets</b>	<b>\$ 38,858,364</b>	<b>\$ 32,126,916</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable (includes related parties of \$2,350 as of September 30, 2010 and \$6,921 as of December 31, 2009)	\$ 1,058,124	\$ 1,187,201
Accrued expenses	717,878	590,600
Other current liabilities	29,726	33,285
<b>Total Current Liabilities</b>	<b>1,805,728</b>	<b>1,811,086</b>
<b>Long Term Liabilities:</b>		
Deferred rent	78,228	—
<b>Total Long Term Liabilities</b>	<b>78,228</b>	<b>—</b>
<b>Total Liabilities</b>	<b>1,883,956</b>	<b>1,811,086</b>
<b>COMMITMENTS AND CONTINGENCIES (Note 7)</b>		
<b>Stockholders' Equity</b>		
Preferred stock — \$.10 par value; authorized 10,000,000 shares; issued and outstanding: none		
Common stock — \$.001 par value; authorized 45,000,000 shares at September 30, 2010 and 30,000,000 at December 31, 2009; issued and outstanding 25,230,535 shares at September 30, 2010 and 22,354,317 at December 31, 2009	25,231	22,354
Additional paid-in capital	130,766,982	109,513,582
Accumulated deficit	(93,817,805)	(79,220,106)
<b>Stockholders' Equity</b>	<b>36,974,408</b>	<b>30,315,830</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 38,858,364</b>	<b>\$ 32,126,916</b>

\* Derived from the audited balance sheet as of December 31, 2009

See accompanying notes to the financial statements

**MELA SCIENCES, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(unaudited)**

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2010</u>	<u>2009</u>	<u>2010</u>	<u>2009</u>
Operating expenses:				
Research and development	\$ 2,936,671	\$ 2,801,208	\$ 8,276,430	\$ 7,636,224
General and administrative	2,033,172	2,262,571	6,352,492	5,361,123
Operating loss	(4,969,843)	(5,063,779)	(14,628,922)	(12,997,347)
Interest income	9,741	7,589	13,702	42,357
Other income	4,998	8,329	17,521	82,445
Net loss:	<u>\$ (4,955,104)</u>	<u>\$ (5,047,861)</u>	<u>\$ (14,597,699)</u>	<u>\$ (12,872,545)</u>
Basic and diluted net loss per common share	<u>\$ (0.20)</u>	<u>\$ (0.26)</u>	<u>\$ (0.62)</u>	<u>\$ (0.70)</u>
Basic and diluted weighted average number of common shares				
outstanding	<u>25,110,970</u>	<u>19,760,367</u>	<u>23,636,446</u>	<u>18,358,579</u>

See accompanying notes to the financial statements

**MELA SCIENCES, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(unaudited)**

	<u>Nine Months Ended September 30,</u>	
	<u>2010</u>	<u>2009</u>
Cash flows from operating activities:		
Net loss	\$(14,597,699)	\$(12,872,545)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	396,878	233,599
Noncash compensation	562,799	410,621
Gain on disposal of fixed assets	(27)	
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	271,806	(34,904)
Increase in deferred rent	78,228	—
(Decrease) increase in accounts payable and accrued expenses	(1,799)	30,054
Decrease in deferred income	—	(36,085)
(Decrease) increase in other current liabilities	(3,559)	1,369
Increase in other assets	(289,705)	(2,724)
<b>Net cash used in operating activities</b>	<b><u>(13,583,078)</u></b>	<b><u>(12,270,615)</u></b>
Cash flows from investing activities:		
Purchases of property and equipment	(1,052,835)	(245,054)
Proceeds from sale of fixed assets	1,500	—
Sale of marketable securities	—	397,380
<b>Net cash (used in) provided by investing activities</b>	<b><u>(1,051,335)</u></b>	<b><u>152,326</u></b>
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	1,717,703	289,479
Net proceeds related to public offering	15,255,671	13,750,407
Proceeds from Committed Equity Financing Facility	3,750,000	7,977,000
Expenses related to Committed Equity Financing Facility	(6,717)	(189,523)
<b>Net cash provided by financing activities</b>	<b><u>20,716,657</u></b>	<b><u>21,827,363</u></b>
Net increase in cash and cash equivalents	6,082,244	9,709,074
Cash and cash equivalents at beginning of period	29,673,420	15,069,939
<b>Cash and cash equivalents at end of period</b>	<b><u>\$ 35,755,664</u></b>	<b><u>\$ 24,779,013</u></b>
<b>Supplemental Schedule of Non-cash Investing and Financing Activities</b>		
Unrealized gain on marketable securities	\$ —	\$ 6,868
Deferred financing costs charged to additional paid-in capital	\$ 23,179	\$ 49,115

See accompanying notes to the financial statements

**MELA SCIENCES, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(In thousands, except for share and per share data)**  
**(unaudited)**

**1. ORGANIZATION AND BASIS OF PRESENTATION**

MELA Sciences, Inc. (formerly Electro-Optical Sciences, Inc.) a Delaware corporation (the “Company”) is a medical device company focused on the design, development and commercialization of a non-invasive, point-of-care (in the doctor’s office) instrument to assist in the early diagnosis of melanoma. The Company’s flagship product, MelaFind<sup>®</sup>, features a hand-held imaging device that emits light of multiple wavelengths to capture images of suspicious pigmented skin lesions and extract data. The data are then analyzed utilizing image processing classification algorithms, ‘trained’ on our proprietary database of melanomas and benign lesions, to provide information to assist in the management of the patient, including information useful in the decision of whether to biopsy the lesion.

The components of the MelaFind<sup>®</sup> system include:

- a *hand-held imaging device*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- a *proprietary database* of pigmented skin lesions, which we believe to be the largest in the U.S.; and
- *lesion classifiers*, which are sophisticated mathematical algorithms that extract lesion feature information and classify lesions.

The MelaFind<sup>®</sup> pre-market approval (“PMA”) application was filed in June 2009 and is under review at the U.S. Food and Drug Administration (the “FDA” or the “Agency”). The pivotal trial conducted to establish the safety and effectiveness of MelaFind<sup>®</sup> was performed under the auspices of a Protocol Agreement. In addition, the MelaFind<sup>®</sup> PMA has been granted Expedited Review by the FDA. On March 19, 2010 the Company received a series of questions from the FDA and was notified that the MelaFind<sup>®</sup> PMA was not approvable at that time. In addition, the Company was advised that the review process had been extended by a period of up to 180 days following the submission of our response to the FDA action letter. Since receiving the questions from the FDA on March 19, the Company has had a series of interactions with the Agency, a draft response was submitted to the FDA in mid-April, and in-person meetings were subsequently held with the Agency to clarify several questions and the final formal response to all questions provided by the FDA was submitted to the Agency on May 7, 2010. The FDA has informed the Company that the scheduled date for the MelaFind<sup>®</sup> Panel Meeting is November 18, 2010.

Upon obtaining approval from the FDA, we plan to launch MelaFind<sup>®</sup> commercially in the United States. The Company is also continuing its efforts with European regulatory agencies to obtain a CE mark for MelaFind<sup>®</sup>, and is conducting market research activities that will facilitate commercialization in Europe and other countries.

To date the Company has not generated any revenues from MelaFind<sup>®</sup>.

The Company anticipates that it will continue to incur net losses for the foreseeable future in the development, obtaining of regulatory approval and commercialization of the MelaFind<sup>®</sup> device. From inception, the Company financed operations primarily through the sale of convertible preferred stock and subsequently sold common stock as part of an initial public offering in October 2005, two private placements (in November 2006 and August 2007), two registered direct offerings (in August 2008 and July 2009), and pursuant to a Committed Equity Financing Facility (“CEFF”) with Kingsbridge Capital Limited in the second half of 2009 and first quarter of 2010. In addition, the Company received net proceeds of approximately \$15.3 million through the sale of common stock pursuant to a public offering which closed July 6, 2010.

Management believes that the cash and cash equivalents available at September 30, 2010 will be sufficient to fund the Company’s anticipated level of operations for at least the next twelve months.

The Company faces certain risks and uncertainties which are present in many emerging medical device companies regarding future profitability, ability to obtain future capital, protection of patents and intellectual property rights, competition, rapid technological

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change, government regulations, changing health care marketplace, recruiting and retaining key personnel, and reliance on third party manufacturing organizations.

As of September 30, 2010, the Company's total of cash and cash equivalents was approximately \$35.8 million. The Company may require additional funds to achieve significant commercialization of MelaFind®. However, there can be no assurances that the Company will be able to raise additional financing in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term. In the event that the Company is unable to raise additional funds, the Company has the ability and intent to reduce certain discretionary expenditures.

The unaudited condensed financial statements included herein have been prepared from the books and records of the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for reporting on Form 10-Q. The information and note disclosures normally included in complete financial statements prepared in accordance with generally accepted accounting principles in the United States ("GAAP") have been condensed or omitted pursuant to such rules and regulations. The interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

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

## **2. COMPREHENSIVE LOSS**

Comprehensive loss includes net loss and unrealized gains and losses on available-for-sale marketable securities. Cumulative unrealized gains and losses on available-for-sale marketable securities are reflected as accumulated other comprehensive gain or loss in stockholders' equity on the Company's condensed balance sheet.

For the three months ended September 30, 2010 both comprehensive loss and net loss were \$4,955 as the Company has not held any available-for-sale marketable securities in 2010. For the three months ended September 30, 2009, both comprehensive loss and net loss were \$5,048 as the Company did not hold any available-for-sale marketable securities during the period.

For the nine months ended September 30, 2010, both comprehensive loss and net loss were \$14,598 as the Company has not held any available-for-sale marketable securities in 2010. For the nine months ended September 30, 2009, comprehensive loss was \$12,866 which included a net loss of \$12,873 and an unrealized gain on available-for-sale marketable securities of \$7.

## **3. USE OF ESTIMATES**

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

## **4. RECENT ACCOUNTING PRONOUNCEMENTS**

In January 2010, the FASB issued ASU 2010-6, an update that improves the requirements related to Fair Value Measurements and Disclosures Subtopic 820-10 of the FASB Accounting Standards Codification originally issued as FASB Statement 157. This update requires enhanced disclosures about transfers between Level 1 and Level 2 assets and the disaggregated activity in the roll forward for Level 3 Fair Value measurements. Except for the detailed Level 3 roll-forward disclosures, these new disclosures are effective for fiscal years beginning after December 15, 2009 and for interim periods within those fiscal years. The requirement to provide detailed disclosures about purchases, sales, issuances, and settlements in the roll-forward activity for Level 3 Fair Value measurements is effective for interim and annual reporting periods beginning after December 31, 2010. The Company does not expect the adoption of ASU 2010-6 to have a material impact on the Company's financial statements.

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## 5. NET LOSS PER COMMON SHARE

Basic earnings per share (“EPS”) excludes dilution for potentially dilutive securities and is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to dilutive options, warrants and other potential common shares outstanding during the period. Diluted net loss per common share is equal to the basic net loss per common share since all potentially dilutive securities are anti-dilutive for each of the periods presented. Potential common stock equivalents excluded consist of stock options and warrants which are summarized as follows:

	September 30,	
	2010	2009
Common stock options	2,171,273	2,038,073
Warrants	614,906	1,297,985
Total	2,786,179	3,336,058

## 6. STOCK-BASED COMPENSATION

The Company has one stock-based compensation plan under which the Board of Directors may currently grant incentives to employees, consultants, directors, officers and collaborating scientists in the form of incentive stock options, nonqualified stock options and restricted stock awards. The Company also has two other stock-based compensation plans pursuant to which stock options are outstanding but no new grants may be made.

Stock awards under the Company’s stock option plans have been granted at prices which are no less than the market value of the stock on the date of the grant. Options granted under the 2005 Stock Incentive Plan (2005 Plan) are generally time-based or performance-based, and vesting varies accordingly. Options under this plan expire in up to a maximum of ten years from the date of grant. Since the Company adopted the 2005 Plan, awards may not be granted under the Company’s previous stock option plans.

The compensation expense recognized in the condensed Statement of Operations in the third quarter of 2010 and 2009 for stock options amounted to \$197 (of which \$12 relates to performance milestones) and \$185 (of which \$25 relates to performance milestones), respectively. For the nine months ended September 2010 and 2009 compensation expense for stock options amounted to \$563 (of which \$23 relates to performance milestones) and \$411 (of which \$38 relates to performance milestones), respectively. Cash received from options and warrants exercised under all share-based payment arrangements for the three months ended September 30, 2010 and 2009 were \$0 and \$158, respectively, and for the nine month periods ended September 30, 2010 and 2009 were \$1,718 and \$289 respectively.

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

	For the Nine Months Ended September 30, 2010	For the Nine Months Ended September 30, 2009
Expected life	5-10 years	5 years
Expected volatility	61-67%	60%
Risk-free interest rate	2.26-3.56%	1.69-2.54%
Dividend yield	0%	0%

The expected life of the options is based on the observed and expected time to full-vesting, forfeiture and exercise. Groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. Starting with the three month period ending September 30, 2009, the expected volatility percentage is stated as calculated rather than as implied. The expected volatility assumptions were determined based upon the historical volatility of the Company’s daily closing stock price. The calculated expected volatility approximates implied volatility from other publicly-traded stock that was established at the time of our initial public offering (“IPO”). The risk-free interest rate is based on the continuous rates provided by the U.S. Treasury with a term equal to the expected life of the option. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

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At September 30, 2010, stock options to purchase 2,171,273 shares of common stock at exercise prices ranging from \$1.00 to \$11.11 per share are outstanding and exercisable at various dates through 2020.

During the three months and nine months ended September 30, 2010, the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was \$5.03 and \$4.73. For the three and nine month period ended September 30, 2009, the weighted average fair value of options granted was \$4.01 and \$3.80, respectively.

For the three and nine months ended September 30, 2010, the total intrinsic value of options exercised was \$0, and \$18, respectively. For the three and nine months ended September 30, 2009, the total intrinsic value of options exercised was \$300, and \$428, respectively.

The status of the Company's stock option plans at September 30, 2010 is summarized in the following:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2009	2,031,023	\$ 5.09	5.2	
Granted	197,800	6.85	8.4	
Exercised	(5,925)	4.40	—	
Forfeited or expired	(51,625)	5.56	—	
Outstanding at September 30, 2010	<u>2,171,273</u>	\$ 5.24	4.9	\$ 3,534
Vested and exercisable at September 30, 2010	<u>921,710</u>	\$ 5.17	2.9	\$ 1,427

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted- Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted- Average Exercise Price
\$0.01-\$1.00	55,971	2.1 years	\$ 1.00	55,971	\$ 1.00
\$1.01-\$4.50	1,096,777	7.0 years	\$ 3.85	327,739	\$ 3.90
\$4.51-\$11.11	1,018,525	2.8 years	\$ 6.96	538,000	\$ 6.38
\$0.01-\$11.11	<u>2,171,273</u>	4.9 years	\$ 5.24	<u>921,710</u>	\$ 5.17

As of September 30, 2010, of the total 2,171,273 options outstanding, 1,249,563 have not vested. Of this total unvested amount, 913,813 options will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. The weighted average vesting period for the non-milestone, non-vested awards not yet recognized is 2.0 years.

As of September 30, 2010, of the \$3,491 of total unrecognized compensation cost related to unvested options to be recognized, \$2,902 is to be recognized over a period to be determined by performance-based milestones, and \$589 is to be recognized over the requisite service period through 2015.

As of September 30, 2010, there were 1,608,076 shares available for future grants under the Company's 2005 Plan.

## 7. COMMITMENTS AND CONTINGENCIES

The Company is obligated under a seven year non-cancelable operating lease for office, lab, and manufacturing space expiring December 2016. The approximate aggregate minimum future payments due under this lease are as follows:

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Year ended December 31,	
2010 remaining three months	\$ 89
2011	382
2012	410
2013	439
2014	455
2015	455
2016	456
	<u>\$ 2,686</u>

Rental payments are recognized as rent expense on a straight-line basis over the term of the lease. In addition to rents due under this lease agreement, the Company is obligated to pay additional facility charges including utilities, taxes, and operating expenses. The Company also leases certain office equipment under non-cancelable operating leases which expire at various times through 2011.

Rental expense totaled approximately \$104 and \$96 for the three month periods ended September 30, 2010 and 2009 respectively and approximately \$312 and \$286 for the nine month periods ended September 30, 2010 and 2009 respectively.

ASKION GmbH (“ASKION”), located in Gera Germany, which specializes in precision optics, is an integral member of the MelaFind<sup>®</sup> development team and the Company expects to continue to work with ASKION for the foreseeable future. ASKION produced the MelaFind<sup>®</sup> hand-held imaging devices used in our pivotal clinical trials and is currently building additional units and performing other additional developmental activities.

Beginning in August 2006, the Company, primarily through ASKION, engaged Carl Zeiss Jena GmbH (“Zeiss”) to build the lenses and assemblies, as well as provide certain technical consulting, for the MelaFind<sup>®</sup> units which have been used in the Company’s pivotal clinical trials. This work has been performed from 2007 through the present, and is expected to continue on commercial MelaFind<sup>®</sup> units throughout 2011.

The Company has an employment agreement with its President and Chief Executive Officer, Dr. Gulfo, which provides for an annual base salary, stock options and discretionary performance bonuses. The agreement, which provides for automatic one-year renewal terms, currently runs through the end of 2010.

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.

## **8. STOCKHOLDERS’ EQUITY**

On October 31, 2006, the Company entered into securities purchase agreements and a registration rights agreement with certain accredited investors for the private placement of 2,312,384 shares of the Company’s common stock and warrants to purchase up to 346,857 shares of the Company’s common stock for aggregate gross proceeds of approximately \$13.2 million and net proceeds of approximately \$12.5 million. Pursuant to the securities purchase agreements, for a purchase price of \$5.70 each investor received one share of the Company’s common stock and a warrant to purchase 0.15 of a share of the Company’s common stock. The warrants are five-year warrants with an exercise price of \$6.70 per share. In accordance with the terms of these warrants, on January 5, 2010 the Company required the holders to exercise their warrants within 30 days. As a result, warrants to purchase 173,963 shares of the Company’s common stock, representing all of the outstanding 2006 warrants, were exercised resulting in gross proceeds to the Company of \$1.165 million.

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

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

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

In June 2008, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed \$40 million. Management utilized this shelf registration statement in August 2008 by completing a registered direct offering of 2,088,451 shares of the Company's common stock for aggregate gross proceeds of \$11.9 million (\$11 million approximate net proceeds to the Company). In addition, in July 2009, management completed a registered direct offering of 2,400,000 shares of the Company's common stock for aggregate gross proceeds of \$15 million (\$13.75 million approximate net proceeds to the Company). Approximately \$13.1 million remains available under the Company's 2008 shelf registration statement as of September 30, 2010.

In May 2009, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited ("Kingsbridge"), pursuant to which Kingsbridge committed to purchase from time to time at the Company's sole discretion, up to the lesser of \$45 million or 3,327,000 shares of the Company's common stock, prior to May 7, 2012 subject to various conditions for individual sales, including dollar, timing, and trading volume limitations, a minimum market per share price, and other contractual and regulatory requirements.

There is no assurance that the Company will satisfy all the various conditions for individual sales enabling it to use all of the CEFF. In connection with this CEFF, the Company issued a 5 year warrant, exercisable as of November 7, 2009, to Kingsbridge to purchase up to 200,000 shares of the Company's common stock at an exercise price of \$11.35 per share with a Black Scholes Fair Value of \$678. The issuance of this warrant was deemed to be a cost of the offering.

Under the CEFF, during 2009, the Company sold 1,824,941 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately \$9.24, for gross proceeds of approximately \$16.9 million. Under the CEFF, during the nine month period ending September 30, 2010, the Company sold 406,744 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately \$9.22, for gross proceeds of approximately \$3.75 million. A proportionate share of the CEFF originating expenses was allocated to these sales from deferred offering costs. Net of expenses, proceeds from the 2010 sales were approximately \$3.727 million. There were no sales under the CEFF in the same period a year earlier.

As of September 30, 2010, there were 1,095,315 shares of common stock remaining available for sale under the CEFF, exclusive of the 200,000 outstanding warrants held by Kingsbridge. As of September 30, 2010, legal, accounting, and other costs associated with this agreement approximating \$62 have been deferred and will be charged to equity as a reduction of future proceeds from the CEFF or operations should management decide to abandon the CEFF.

In May 2010, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed \$75 million. The registration statement was declared effective by the SEC on June 1, 2010 (File No. 333-167113). On June 30, 2010, the Company entered into an underwriting agreement, relating to the public offering of 2,200,000 shares of the Company's common stock, at a price to the public of \$7.50 per share less underwriting discounts and commissions. The common stock was offered and sold pursuant to the Company's Prospectus dated June 1, 2010 and the Company's Prospectus Supplement filed with the Securities and Exchange Commission (the "SEC") on June 30, 2010, in connection with a takedown from the Company's effective shelf registration statement. The gross proceeds to the Company from the sale of the Common Stock totaled \$16.5 million. After deducting the underwriters' discounts and commissions and other estimated offering expenses payable by the Company, net proceeds were approximately \$15.3 million. This offering closed on July 6, 2010. Approximately \$58.5 million remains available under the Company's 2010 shelf registration statement as of September 30, 2010.

As of September 30, 2010, the Company had 45,000,000 shares of \$0.001 par value common stock authorized and 25,230,535 shares issued and outstanding; and 10,000,000 shares of \$0.10 par value preferred stock authorized with no preferred shares issued and outstanding.

## **9. WARRANTS**

In connection with the Company's initial public offering in October 2005, the Company issued 150,000 warrants to the underwriters to purchase shares of the Company's common stock at \$6.25 per share. These 5-year warrants became exercisable on October 28, 2006, and 68,125 remain outstanding at September 30, 2010. These warrants expired November 2, 2010.

As previously discussed in connection with the Company's private placements, in November 2006 and August 2007 the Company issued warrants to purchase up to 346,857 and 500,041 shares of the Company's common stock, respectively. At September 30, 2010, none of the 2006 warrants and 346,781 of the 2007 warrants were outstanding. The 2007 outstanding warrants are exercisable for five years at a price of \$8.00 per share.

In addition, in connection with the May 7, 2009 CEFF with Kingsbridge Capital, the Company issued a 5 year warrant to Kingsbridge to purchase up to 200,000 shares of the Company's common stock at an exercise price of \$11.35 per share. These 200,000 warrants are outstanding at September 30, 2010.

Warrants exercised were 0 and 9,684 during the three month periods ended September 30, 2010 and September 30, 2009, respectively. 263,549 and 26,559 warrants were exercised during the nine month periods ended September 30, 2010 and September 30, 2009, respectively.

## **10. RELATED PARTY CONSULTING AGREEMENTS**

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

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

In June 2003, the Company entered into a consulting agreement with Breaux Castleman, the Chairman of the Company's Board of Directors, for consulting services related to the FDA approval of MelaFind<sup>®</sup>, and the Company's business and financial strategy. Under this agreement, Mr. Castleman receives compensation for each month of services rendered. The Company incurred and paid, pursuant to this consulting agreement, \$6 in each of the three month periods ended September 30, 2010 and 2009 and \$18 in each of the nine month periods ended September 30, 2010 and 2009. This consulting agreement is terminable by either party by providing thirty days' prior written notice.

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

Effective as of May 31, 2005, the Company retained Marek Elbaum, Ph.D., the Company's founder and former President and Chief Science and Technology Officer, as the Company's Chief Scientist. In consideration of the services to be provided, the Company agreed to pay Dr. Elbaum a monthly fee of \$15.

In May of 2007 and effective June 1, 2007, Dr. Elbaum and the Company entered into an amended agreement. Under the terms of the amended agreement, Dr. Elbaum was paid a monthly fee of \$9 through January 2009 when the contract terminated.

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

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

This consulting agreement continues to automatically renew for successive one-year terms unless either party terminates the agreement at least 30 days prior to its expiration. The Company made no payments to Dr. Friedman for the nine month period ended September 30, 2010, and paid \$0 and \$40 for the three and nine month periods ended September 30, 2009, respectively.

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

Effective April 1, 2006, the Company entered into an amended and restated consulting agreement with Gerald Wagner, Ph.D., a member of the Company's Board of Directors and its former Acting Chief Operating Officer.

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With the start of the Company's pivotal clinical trial in January 2007, Dr. Wagner transitioned out of his role as the Company's acting Chief Operating Officer and entered into an amended and restated consulting contract with the Company. Under the terms of the amended contract, Dr. Wagner is paid a monthly retainer of \$2.5 and will be paid \$2.5 for each additional consulting day. This amended agreement will end at the option of Dr. Wagner or the Company at any time, by providing fifteen days' prior written notice, or immediately upon the mutual agreement of the Company and Dr. Wagner. The Company incurred consulting costs pursuant to this agreement of \$7.5 and \$22.5 in each of the three and nine month periods ended September 30, 2010 and September 30, 2009, respectively.

### **Consulting Agreement with Anne Egger**

In March 2009, the Company entered into a consulting agreement with Anne Egger for certain consulting services primarily focusing on physician advocacy. The agreement was for an initial term of three months, and has subsequently been extended to run through October 2011, and may be terminated by either party with 30 days notice. Under the terms of the agreement, Ms. Egger is entitled to receive a consulting fee of \$1.6 per day. Ms. Egger was appointed to the Company's Board of Directors as of June 10, 2009. The Company incurred consulting costs pursuant to this agreement of \$10 and \$31 in the three month periods ended September 30, 2010 and September 30, 2009, respectively. The Company incurred consulting costs pursuant to this agreement of \$45 and \$50 in the nine month periods ended September 30, 2010 and September 30, 2009, respectively.

## **11. OTHER INCOME**

During March 2007, the Company entered into an agreement with L'Oreal to study and assess the feasibility of using MELA Sciences' novel multi-spectral imaging technology for the evaluation and differentiation of pigmented skin lesions of cosmetic importance. In December 2008, L'Oreal and the Company agreed on a second amendment to the agreement, for a new three month study. The laboratory and clinical research is being funded by L'Oreal. Pursuant to the agreement, L'Oreal is responsible for all costs and expenses incurred in connection with the feasibility program, and will reimburse MELA Sciences for expenses incurred by MELA Sciences with respect to the Feasibility Program.

At December 31, 2009, the work to be carried out under the agreement was complete and the Feasibility Program concluded. Therefore, no income was earned from the Feasibility Program in the nine months ended September 30, 2010. During the three and nine month periods ended September 30, 2009, the Company earned \$0 and \$34 respectively from L'Oreal as other income under the Feasibility Program.

During April 2005, the Company discontinued all operations associated with its DIFOTI<sup>®</sup> product in order to focus its resources and attention on the development and commercialization of MelaFind<sup>®</sup>. During December 2006, the Company entered into a sale and exclusive licensing agreement with KaVo Dental GmbH ("KaVo"), a leading dental equipment manufacturer, which provides for KaVo to further develop and commercialize DIFOTI<sup>®</sup>. Beginning in July 2008, KaVo is required to pay to the Company a royalty stream based upon the worldwide aggregate net sales of the licensed product, as defined in the license agreement, or a set minimum. For the three and nine months ended September 30, 2010, the Company earned royalty income of \$5 and \$15, respectively. For the three and nine months ended September 30, 2009, the Company was paid royalty income of \$5 and \$15, respectively.

## **12. SUBSEQUENT EVENT**

On October 29, 2010, the Internal Revenue Service awarded the Company a grant under the Qualifying Therapeutic Discovery Project Program. The grant is in the form of a cash payment of \$244 against Research and Development expenses incurred by the Company on MelaFind<sup>®</sup> between January 1, 2009 and May 31, 2010.

ITEM 2.

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

This management's discussion and analysis of financial condition and results of operations is intended to provide information to help you better understand and evaluate our financial condition and results of operations. We recommend that you read this section in conjunction with our unaudited condensed financial statements and accompanying notes included under Part I, Item 1 of this Quarterly Report and our financial statements and accompanying notes in our Annual Report on Form 10-K for the year ended December 31, 2009.

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

**Overview**

We are a medical device company focused on the design and development of a non-invasive, point-of-care instrument to assist in the early diagnosis of melanoma. Our flagship product, MelaFind<sup>®</sup>, features a hand-held imaging device that emits light of multiple wavelengths to capture images of suspicious pigmented skin lesions and extract data. We currently do not have any commercialized products or any significant source of revenue.

We commenced operations in December 1989 as a New York corporation, re-incorporated as a Delaware corporation in September 1997, and changed our name from Electro-Optical Sciences, Inc. to MELA Sciences, Inc. on April 30, 2010. Since our inception, we have generated significant losses. As of September 30, 2010, we had an accumulated deficit of \$93.8 million. We expect to continue to spend significant amounts on the development of MelaFind<sup>®</sup>.

The MelaFind<sup>®</sup> pre-market approval ("PMA") application was filed in June 2009 and is under review at the U.S. Food and Drug Administration (the "FDA" or the "Agency"). The pivotal trial conducted to establish the safety and effectiveness of MelaFind<sup>®</sup> was performed under the auspices of a Protocol Agreement. In addition, the MelaFind<sup>®</sup> PMA has been granted Expedited Review by the FDA. On March 19, 2010 the Company received a series of questions from the FDA and was notified that the MelaFind<sup>®</sup> PMA was not approvable at that time. In addition, the Company was advised that the review process had been extended by a period of up to 180 days following the submission of our response to the FDA action letter. Since receiving the questions from the FDA on March 19, the Company has had a series of interactions with the Agency, a draft response was submitted to the FDA in mid-April, and in-person meetings were subsequently held with the Agency to clarify several questions and the final formal response to all questions provided by the FDA was submitted to the Agency on May 7, 2010. The FDA has informed the Company that the scheduled date for the MelaFind<sup>®</sup> Panel Meeting is November 18, 2010.

Upon obtaining approval from the FDA, we plan to launch MelaFind<sup>®</sup> commercially in the United States. The Company is also continuing its efforts with European regulatory agencies to obtain a CE mark for MelaFind<sup>®</sup>, and is conducting market research activities that will facilitate commercialization in Europe and other countries.

Our revenue for the foreseeable future will depend on the approval by the FDA of MelaFind<sup>®</sup> and the commercialization of MelaFind<sup>®</sup>, and may vary substantially from year to year and quarter to quarter. We believe that period-to-period comparisons of our results of operations may not be meaningful and should not be relied on as indicative of our future performance.

## Liquidity and Capital Resources

On June 26, 2008, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed \$40 million. Management utilized this shelf registration statement in August 2008 by completing a registered direct offering of 2,088,451 shares of the Company's common stock for aggregate gross proceeds of approximately \$11.9 million (\$11 million approximate net proceeds to the Company), and in July 2009 by completing a registered direct offering of 2,400,000 shares of the Company's common stock for aggregate gross proceeds of \$15 million (\$13.75 million approximate net proceeds to the Company). Approximately \$13.1 million remains available under the Company's shelf registration statement as of September 30, 2010.

In May 2009, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited, pursuant to which Kingsbridge committed to purchase from time to time at the Company's sole discretion, up to the lesser of \$45 million or 3,327,000 shares of the Company's common stock, prior to May 7, 2012 subject to various conditions for individual sales, including dollar, timing, and trading volume limitations, a minimum market per share price, and other contractual and regulatory requirements. There is no assurance that the Company will satisfy all the various conditions for individual sales enabling it to use all of the CEFF. In connection with this CEFF, the Company issued a 5 year warrant, exercisable as of November 7, 2009, to Kingsbridge to purchase up to 200,000 shares of the Company's common stock at an exercise price of \$11.35 per share with a Black Scholes Fair Value of \$678. The issuance of this warrant was deemed to be a cost of the offering.

Under the CEFF, during 2009, the Company sold 1,824,941 shares of common stock to Kingsbridge Capital Limited ("Kingsbridge"), at an average per share price of approximately \$9.24, for gross proceeds of approximately \$16.9 million. Under the CEFF, during the nine month period ended September 30, 2010, the Company sold 406,744 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately \$9.22, for gross proceeds of approximately \$3.75 million. A proportionate share of the CEFF originating expenses was allocated to these sales from deferred offering costs. Net of expenses, proceeds from these sales were approximately \$16.8 million and \$3.727 million for 2009 and 2010, respectively.

In May 2010, the Company filed a Form S-3 shelf registration statement for an indeterminate number of shares of common stock, warrants to purchase shares of common stock and units consisting of a combination thereof having an aggregate initial offering price not to exceed \$75 million. The registration statement was declared effective by the SEC on June 1, 2010 (File No. 333-167113). On June 30, 2010, the Company entered into an underwriting agreement, relating to the public offering of 2,200,000 shares of the Company's common stock, at a price to the public of \$7.50 per share less underwriting discounts and commissions. The common stock was offered and sold pursuant to the Company's Prospectus dated June 1, 2010 and the Company's Prospectus Supplement filed with the Securities and Exchange Commission (the "SEC") on June 30, 2010, in connection with a takedown from the Company's effective shelf registration statement. The gross proceeds to the Company from the sale of the Common Stock totaled \$16.5 million. After deducting the underwriters' discounts and commissions and other estimated offering expenses payable by the Company, net proceeds were approximately \$15.3 million. This offering closed on July 6, 2010. Approximately \$58.5 million remains available under the Company's 2010 shelf registration statement as of September 30, 2010.

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

To date, we have not borrowed (other than by issuing convertible notes, all of which have been converted into equity) or financed our operations through equipment leases, financing loans or other debt instruments.

As of September 30, 2010, the Company's total of cash and cash equivalents was approximately \$35.8 million. The Company may require additional funds to achieve significant commercialization of MelaFind®. However, there can be no assurances that the Company will be able to raise additional financing in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term. In the event that the Company is unable to raise additional funds, the Company has the ability and intent to reduce certain discretionary expenditures. Management believes that the cash and cash equivalents available at September 30, 2010 will be sufficient to fund the Company's anticipated level of operations for at least the next twelve months.

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Our cash and cash equivalents at September 30, 2010 are liquid investments in money market accounts and deposits with commercial banks, which are held in amounts that substantially exceed FDIC limits.

### **Cash Flows from Operating Activities (in thousands)**

Net cash used in operations was \$13,583 for the nine months ended September 30, 2010. For the corresponding period in 2009, net cash used in operations was \$12,271. In both periods, cash used in operations was attributable to net losses after an adjustment for non-cash charges related to depreciation/amortization and share-based compensation, and other changes in operating assets and liabilities.

### **Cash Flows from Investing Activities (in thousands)**

For the nine months ended September 30, 2010, there was \$1,051 net cash used in our investing activities, principally for the purchase of leasehold improvements and fixed assets. For the corresponding period in 2009, \$152 net cash was provided by our investing activities principally related to the redemption of marketable securities less purchases of property and equipment.

### **Cash Flows from Financing Activities (in thousands)**

For the nine months ended September 30, 2010, net cash provided by financing activities was \$20,717, representing net proceeds of \$3,743 from the Committed Equity Financing Facility, \$1,718 from the exercise of warrants and options, and net proceeds of \$15,256 from the July 2010 public offering. For the nine months ended September 30, 2009, net cash provided by financing activities was \$21,827. Cash received from the exercise of options and warrants was \$289, net proceeds were \$7,787 from the Committed Equity Financing Facility, and net proceeds were \$13,750 from the July 2009 offering.

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

We face certain risks and uncertainties, which are present in many emerging medical device companies. At September 30, 2010, we had an accumulated deficit of \$93.8 million. We have not commercialized our principal product, MelaFind<sup>®</sup>. We anticipate that we will continue to incur net losses for the foreseeable future as we pursue the regulatory approvals for MelaFind<sup>®</sup>, continue to develop the MelaFind<sup>®</sup> system, expand our corporate infrastructure, and prepare for the potential commercial launch of MelaFind<sup>®</sup>. We do not expect to generate significant product revenue until we successfully obtain PMA approval for and begin selling MelaFind<sup>®</sup>.

If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of planned product research and development and commercialization activities, which could harm our business.

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

- The schedule, costs, and results of our clinical trials;
- The success of our research and development efforts;
- The costs and timing of regulatory approval;
- Reimbursement amounts for the use of MelaFind<sup>®</sup> that we are able to obtain from Medicare and third party payers, or the amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind<sup>®</sup>;
- The cost of commercialization activities, including product marketing and building a domestic direct sales force;
- The emergence of competing or complementary technological developments;
- The costs of filing, prosecuting, defending and enforcing any patent claims and other rights, including litigation costs and the results of such litigation;

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- The costs involved in defending any patent infringement actions brought against us by third parties; and
- Our ability to establish and maintain any collaborative, licensing or other arrangements, and the terms and timing of any such arrangements.

### **Contractual Obligations** (in thousands)

The following table summarizes our outstanding contractual obligations as of September 30, 2010, and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>More than 5 years</u>
Operating leases	\$ 2,686	\$ 375	\$ 835	\$ 907	\$ 569

Our long-term obligations represent a non-cancelable operating lease for our laboratory, assembly, and office space. The lease on approximately 20,000 square feet of office space expires in December 2016.

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

Through the first nine months of 2010, the Company actively supported the FDA's PMA review process, continued to develop procedures and equipment to allow for the efficient manufacture of MelaFind<sup>®</sup>, initiated a program to achieve CE Marking to facilitate entry into the European market and intensified pre-commercialization activities in preparation for product launch. The Company's move into a larger, renovated facility in Irvington N.Y., which began in late 2009, was completed early in 2010.

### **Three Months Ended September 30, 2010 Compared to Three Months Ended September 30, 2009**

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

Research and development ("R&D") expenses experienced an overall increase of \$135 or 5% in the three months ended September 30, 2010 above the comparable period a year earlier. Research and development activities are currently concentrated on addressing the requirements of the FDA review process, the design needs of CE Marking and the commercialized manufacturing needs for product launch after FDA approval. Regulatory/Quality function increased \$125, US and European Development was up \$92 while Clinical/Technical Support decreased \$86 from the same period a year earlier

#### **General and Administrative Expense**

General and Administrative ("G&A") expenses experienced an overall decrease of \$229 or 10% for the three months ended September 30, 2010 below the comparable period a year earlier. The movement of the scheduled FDA Advisory Panel Meeting from August to November resulted in a re-scheduling of certain Marketing and Executive programs. Marketing decreased \$144 and Executive decreased \$56 from the same period in 2009.

#### **Interest Income**

Interest income for the three months ended September 30, 2010 increased to \$10 from \$8 in the comparable period of 2009. Interest income increased as there was more cash available to earn interest in 2010 than in over 2009.

#### **Other Income**

Other income decreased by \$3 in 2010 from a year earlier.

### **Nine Months Ended September 30, 2010 Compared to Nine Months Ended September 30, 2009**

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

Research and development ("R&D") expenses experienced an overall increase of \$640 or 8% in the nine months ended September 30, 2010 above the comparable period a year earlier. Regulatory/Quality function's consulting costs have increased \$151, R&D labor increased \$321 at ASKION in Germany where added emphasis has been placed on parts qualification and testing regimens for the MelaFind<sup>®</sup> hand-held devices, as well as product improvement costs which increased \$180.

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**General and Administrative Expense**

General and Administrative (“G&A”) expenses experienced an overall increase of \$991 or 18% for the nine months ended September 30, 2010 above the comparable period a year earlier. Within G&A, marketing costs represented \$269 of the total increase. Significant to the increase in marketing costs are the addition of sales management and administrative personnel of \$175 and costs related to industry conferences of \$110.

The Information Technology (“IT”) function added two employees in 2010 over 2009 related to implementing significant upgrades in the IT processing capabilities of the Company. Increases in information technology costs include compensation costs of \$135 and computer supplies and maintenance costs of \$68.

Other year-to-year increases in general and administrative costs for the nine months ended September 30, 2010 include increased depreciation and amortization of \$166 associated with the new location build out and computer infrastructure acquisitions, professional fees of \$208, office supplies of \$86, and share based compensation of \$82.

**Interest Income**

Interest income for the nine months ended September 30, 2010 decreased to \$14 from \$42 in the comparable period of 2009. Interest income fell as a reflection of the deterioration of interest rates available for investment of our cash balances.

**Other Income**

Other income decreased by \$65 in 2010 from a year earlier primarily due to the L’Oreal feasibility study no longer being active or providing income for the Company in the first nine months of 2010.

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

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

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

**Revenue Recognition**

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

**Stock-Based Compensation**

We record compensation expense associated with stock options and other forms of equity compensation in accordance with FASB ASC 718, *Stock Compensation* (“FAS ASC 718”) as interpreted by SEC Staff Accounting Bulletins No. 107 and No. 110. A compensation charge is recorded when it is probable that performance conditions will be satisfied. The probability of vesting is updated at each reporting period and compensation is adjusted prospectively.

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

Options or warrants issued to non-employees for goods or services are recorded at fair value and accounted for in accordance with FASB ASC 505, *Equity-based Payments to Non-employees*.

### **Accrued Expenses**

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

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

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

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

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

### **Recent Accounting Pronouncements**

In January 2010, the FASB issued ASU 2010-6, an update that improves the requirements related to Fair Value Measurements and Disclosures Subtopic 820-10 of the FASB Accounting Standards Codification originally issued as FASB Statement 157. This update requires enhanced disclosures about transfers between Level 1 and Level 2 assets and the disaggregated activity in the roll forward for Level 3 Fair Value measurements. Except for the detailed Level 3 roll-forward disclosures, these new disclosures are effective for fiscal years beginning after December 15, 2009 and for interim periods within those fiscal years. The requirement to provide detailed disclosures about purchases, sales, issuances, and settlements in the roll-forward activity for Level 3 Fair Value measurements is effective for interim and annual reporting periods beginning after December 31, 2010. The Company does not expect the adoption of ASU 2010-6 to have a material impact on the Company's financial statements.

## **ITEM 3.**

### **Quantitative and Qualitative Disclosures about Market Risk**

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

## ITEM 4.

### Controls and Procedures

#### Evaluation of disclosure controls and procedures

Based on their evaluation as of September 30, 2010, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, were effective to ensure that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

#### Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Limitations on the effectiveness of controls

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

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings, nor, to our knowledge, is any material legal proceeding threatened against us. From time to time, we may be a party to certain legal proceedings, incidental to the normal course of our business.

### Item 1A. Risk Factors

*Our business and operations entail a variety of serious risks and uncertainties, including those described in Item 1A of our Form 10-K for the year ended December 31, 2009. In addition, the following risk factors have changed during the nine months ended September 30, 2010:*

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

We began operations in December 1989. At that time, we provided research services, mostly to US government agencies, on classified projects. We have financed our operations since 1999 primarily through the sale of our equity securities and have devoted substantially all of our resources to research and development relating to MelaFind®. Our net loss for the three months and nine months ended September 30, 2010 was approximately \$5 million and \$14.6 million, respectively, and as of September 30, 2010, we had an accumulated deficit of approximately \$93.8 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind®. If we receive PMA approval for MelaFind® from the FDA, we expect to incur significant sales and marketing expenses, which will require additional funding, and manufacturing expenses. Additionally, our general and administrative expenses have also increased due to the additional operational and regulatory responsibilities applicable to public companies. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

As of September 30, 2010, we had approximately \$35.8 million in cash and cash equivalents. Our operations have consumed substantial amounts of cash for each of the last eight years. The Company will require additional funds to pursue regulatory approvals and to achieve significant commercialization of MelaFind®. However, there can be no assurances that the Company will be able to raise additional

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capital in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term.

Any additional financing may be dilutive to stockholders, or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

- the schedule, costs, and results of our clinical trials;
- the success of our research and development efforts;
- the costs and timing of regulatory approval;
- reimbursement amounts for the use of MelaFind<sup>®</sup> that we are able to obtain from Medicare and third-party payers, or the amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind<sup>®</sup>;
- the cost of commercialization activities, including product marketing and building a domestic direct sales force;
- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other rights, including litigation costs and the results of such litigation;
- the costs involved in defending any patent infringement actions brought against us by third parties; and
- our ability to establish and maintain any collaborative, licensing or other arrangements, and the terms and timing of any such arrangements.

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

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

Our stock price is likely to be volatile. Between October 28, 2005 (the date of our initial public offering) and September 30, 2010, our stock price has ranged from \$2.29 to \$12.24 per share. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock:

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

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- product liability claims and litigation against us or our competitors;
- the departure of key personnel;
- the strength of our balance sheet;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of and third-party reimbursement in the US and other countries;
- changes in accounting principles or practices;
- general economic, industry and market conditions; and
- future sales of our common stock.

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

### ***Climate control policy changes, including legislation pending in the U.S. Congress and negotiated international treaties, could have an impact on our Company.***

We cannot predict whether climate control legislation will be enacted and treaties ratified, the final form any legislation or treaties might take, or the effects of such legislation or treaties. If climate control legislation is enacted or treaties ratified, our operations or the operations of our suppliers could be adversely impacted affecting our ability to successfully launch MelaFind® in the U.S. marketplace.

### ***Results could be impacted by the effects of, and changes in, world-wide economic and capital market conditions***

The Company's business may be adversely affected by factors in the United States and other countries that are beyond its control, such as disruptions in the financial markets or downturns in economic activity. The current world-wide economic conditions could have an adverse impact on the availability and cost of capital, interest rates, tax rates, or regulations.

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

In May 2009, the Company entered into a committed equity financing facility ("CEFF") with Kingsbridge Capital Limited, pursuant to which Kingsbridge committed to purchase from time to time at the Company's sole discretion, up to the lesser of \$45 million or 3,327,000 shares of the Company's common stock, prior to May 7, 2012 subject to various conditions for individual sales, including dollar, timing, and trading volume limitations, a minimum market per share price, and other contractual and regulatory requirements. The proceeds from the sale of these securities will be used by the Company to fund product development and for general corporate expenses. There is no assurance that the Company will satisfy all the various conditions for individual sales enabling it to use all of the CEFF.

Under the CEFF, during the nine month period ending September 30, 2010, the Company sold 406,744 shares of common stock to Kingsbridge Capital Limited, at an average per share price of approximately \$9.22, for gross proceeds of approximately \$3.75 million. These shares were issued in reliance upon an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering and Regulation D of the Securities Act.

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

Not applicable.

## **Item 4. Reserved**

## **Item 5. Other Information**

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

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**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Title</b>
31.1#	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2#	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1#	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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# Filed herewith

**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.

**MELA SCIENCES, INC.**

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

Date: November 5, 2010

**EXHIBIT INDEX**

Exhibit No.	Description
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

I, Joseph V. Gulfo, certify that:

1. I have reviewed this report on Form 10-Q of MELA Sciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operations of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2010

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

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

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

I, Richard I. Steinhart, certify that:

1. I have reviewed this report on Form 10-Q of MELA Sciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operations of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2010

/s/ Richard I. Steinhart

Richard I. Steinhart

Vice President and Chief Financial Officer

(Principal Accounting and Financial Officer)

**MELA 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 MELA 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, 2010 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph V. Gulfo

Joseph V. Gulfo  
President and Chief Executive Officer  
(Principal Executive Officer)  
November 5, 2010

/s/ Richard I. Steinhart

Richard I. Steinhart  
Vice President & Chief Financial Officer  
(Principal Accounting and Financial Officer)  
November 5, 2010

\* A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to MELA Sciences, Inc. and will be retained by MELA 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 MELA 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.