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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, 2011

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

For the transition period from to

Commission file number 000 — 51481

MELA SCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**13-3986004**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
50 South Buckhout Street, Suite 1 Irvington, New York	**10533**
(Address of Principal Executive offices)	*(Zip Code)*

Registrant's Telephone Number, including area code:
(914) 591-3783
(Former name if changed since last report)

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

Yes ☑ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant 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 o

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

Yes o No ☑

As of October 31, 2011: 25,262,538 shares of the Registrant's common stock were outstanding.

MELA Sciences, Inc.
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MELA SCIENCES, INC.
CONDENSED BALANCE SHEETS

	September 30, 2011 (unaudited)	December 31, 2010 *
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 16,999,279	$ 30,520,812
Prepaid expenses and other current assets	859,708	523,672
Total Current Assets	17,858,987	31,044,484
Property and equipment, net	1,725,615	2,073,602
Patents and trademarks, net	62,183	71,108
Deferred financing costs	62,391	62,391
Other assets	586,498	337,705
Total Assets	$ 20,295,674	$ 33,589,290
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 629,996	$ 1,096,505
Accrued expenses (includes related parties of $3,755 as of September 30, 2011)	659,842	559,975
Other current liabilities	28,250	29,538
Total Current Liabilities	1,318,088	1,686,018
Long Term Liabilities:		
Deferred rent	129,738	104,304
Total Long Term Liabilities	129,738	104,304
Total Liabilities	1,447,826	1,790,322
COMMITMENTS, CONTINGENCIES and LITIGATION (Note 6)		
Stockholders' Equity		
Preferred stock — $.10 par value; authorized 10,000,000 shares; issued and outstanding: none		
Common stock — $.001 par value; authorized 45,000,000 shares; issued and outstanding 25,262,538 shares at September 30, 2011 and December 31, 2010	25,263	25,263
Additional paid-in capital	133,827,586	130,916,326
Accumulated deficit	(115,005,001)	(99,142,621)
Total Stockholders' Equity	18,847,848	31,798,968
Total Liabilities and Stockholders' Equity	$ 20,295,674	$ 33,589,290

* Derived from the audited balance sheet as of December 31, 2010

See accompanying notes to the financial statements

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

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Operating expenses:				
Research and development	$ 2,437,811	$ 2,936,671	$ 7,634,493	$ 8,276,430
General and administrative	3,689,991	2,033,172	8,291,170	6,352,492
Operating loss	(6,127,802)	(4,969,843)	(15,925,663)	(14,628,922)
Interest income	10,729	9,741	45,194	13,702
Other income, net	6,419	4,998	18,089	17,521
Net loss	$ (6,110,654)	$ (4,955,104)	$ (15,862,380)	$ (14,597,699)
Basic and diluted net loss per common share	$ (0.24)	$ (0.20)	$ (0.63)	$ (0.62)
Basic and diluted weighted average number of common shares outstanding	25,262,538	25,110,970	25,262,538	23,636,446

See accompanying notes to the financial statements

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

	Nine Months Ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net loss	$ (15,862,380)	$ (14,597,699)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	415,592	396,878
Noncash compensation	2,911,260	562,799
Gain on disposal of fixed assets		(27)
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	(336,036)	271,806
Decrease in accounts payable and accrued expenses	(366,642)	(1,799)
Increase in other assets	(248,793)	(289,705)
Increase in deferred rent	25,434	78,228
Decrease in other current liabilities	(1,288)	(3,559)
Net cash used in operating activities	(13,462,853)	(13,583,078)
Cash flows from investing activities:		
Purchases of property and equipment	(58,680)	(1,052,835)
Proceeds from sale of fixed assets	—	1,500
Net cash used in investing activities	(58,680)	(1,051,335)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	26,070
Proceeds from exercise of stock warrants		1,691,633
Proceeds from public offering		16,500,000
Expenses related to public offering	—	(1,244,329)
Proceeds from Committed Equity Financing Facility	—	3,750,000
Expenses related to Committed Equity Financing Facility	—	(6,717)
Net cash provided by financing activities	—	20,716,657
Net (decrease) increase in cash and cash equivalents	(13,521,533)	6,082,244
Cash and cash equivalents at beginning of period	30,520,812	29,673,420
Cash and cash equivalents at end of period	$ 16,999,279	$ 35,755,664
Supplemental Schedule of Non-cash Investing and Financing Activities		
Deferred financing costs charged to additional paid-in capital	$ —	$ 23,179

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., 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 aid in the detection of early melanoma. The Company's flagship product, MelaFind®, features a hand-held imaging device that emits light of multiple wavelengths to capture images of suspicious pigmented skin lesions and extract data. The data are then analyzed 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's disease, including information useful in the decision of whether to biopsy the lesion.

The components of the MelaFind® system include:

- a *hand-held imaging device*, which employs high precision optics and multi-spectral illumination (multiple colors of light including near infra-red);
- 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.

On November 1, 2011, the Company received written approval from the U.S. Food and Drug Administration ("FDA") of the Company's MelaFind® Pre-Market Approval ("PMA") application.

The MelaFind® PMA was submitted to the FDA in June 2009, and had been granted expedited review by the FDA. A pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a binding Protocol Agreement; all study end points were met. The results of the pivotal study were published in the *Archives of Dermatology* in October 2010 (on-line) and February 2011 (print). The PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel ("Panel") in November of 2010. The Panel voted favorably on all three questions posed by the FDA.

In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. In May 2011, the Company filed a second PMA amendment containing a training program for clinicians, an outline of which was presented at the Panel meeting. Also in May 2011, the Company submitted a Citizen's Petition to the FDA requesting that the Commissioner of the FDA enforce the binding Protocol Agreement, as well as FDA laws and regulations, in completing the review of the MelaFind® PMA.

The Company received an Approvable Letter from the FDA for the MelaFind® PMA application on September 22, 2011. Subsequent to September 30, 2011, the Company received an Approval Letter from the FDA on November 1, 2011 approving the MelaFind® PMA application. Based upon receipt of FDA approval of the MelaFind® PMA application, the Company withdrew its Citizen's Petition filed with the FDA in May 2011.

With FDA approval received, the Company plans to launch MelaFind® commercially in the United States during the first quarter of 2012.

In August of 2011, the Company received the International Organization for Standardization ("ISO") 13485 certification of the Company's comprehensive management system for the design

and manufacture of medical devices. On September 6, 2011, the Company received Conformite Europeenne ("CE") Mark approval for MelaFind®. With CE Mark approval, the Company has the ability to market MelaFind® to dermatologists across the European Union and in certain other countries.

The Company plans to launch MelaFind® commercially in Germany during the first quarter of 2012.

To date the Company has not generated any revenues from MelaFind®. The Company anticipates that it will continue to incur net losses for the foreseeable future in the development and commercialization of the MelaFind® device. From inception, the Company 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 $15.2 million through the sale of common stock pursuant to a public offering which closed July 6, 2010.

The Company faces certain risks and uncertainties which are present in many emerging medical device companies regarding future profitability, ability to obtain future capital, protection of patents and intellectual property rights, competition, rapid technological change, government regulations, changing health care marketplace, recruiting and retaining key personnel, and reliance on third party manufacturing organizations.

As of September 30, 2011, the Company's total of cash and cash equivalents was approximately $17.0 million. Management believes that with FDA and CE Mark approval this cash balance will be sufficient to fund the Company's controlled launches in the northeast U.S. and Germany and the anticipated level of operations for at least the next twelve months. However, the Company will require additional funds to achieve significant commercialization of MelaFind®. 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, 2010.

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. 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.

With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, the Company deemed it probable that it would subsequently receive PMA approval from the FDA for the MelaFind® PMA application. Accordingly, $1,889 in non-cash compensation expense was recorded as of September 30, 2011 representing options on which the performance vesting milestone is related to FDA approval. Those options remain as unvested on all option tables in this report on Form 10-Q, as vesting took place at the time approval was received.

3. RECENT ACCOUNTING PRONOUNCEMENTS

None

4. NET LOSS PER COMMON SHARE

Basic net loss per common share 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 net loss per common share 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,	
	2011	2010
Common stock options	2,126,804	2,171,273
Common stock warrants	546,781	614,906
Total	2,673,585	2,786,179

5. STOCK-BASED COMPENSATION

The Company has one stock-based compensation plan, the 2005 Stock Incentive Plan (“2005 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 one other stock-based compensation plan pursuant to which stock options are outstanding but from which 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 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.

The non-cash compensation expense recognized in the Statement of Operations in the third quarter of 2011 and 2010 for stock options amounted to $2,177 (of which $2,031 relates to performance milestones) and $197 (of which $12 relates to performance milestones), respectively. With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, approval of the PMA application by the FDA was deemed by the Company to be probable and $1,889 in non-cash compensation expense was recorded in the third quarter of 2011 for options which related to the FDA approval milestone.

For the nine months ended September 2011 and 2010, non-cash compensation expense recognized in the Statement of Operations for stock options amounted to $2,911 (of which $2,059 relates to performance milestones) and $563 (of which $23 relates to performance milestones), respectively. With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, approval of the PMA application by the FDA was deemed by the Company to be probable and $1,889 in non-cash compensation expense was recorded for the nine months ended September 30, 2011 for options which related to the FDA approval milestone.

There was no cash received from options and warrants exercised under all share-based payment arrangements for the three month periods ended September 30, 2011 and 2010, nor for the nine month period ended September 30, 2011. Cash received from options and warrants exercised under all share-based payment arrangements for the nine months ended September 30, 2010 was $1,718.

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, 2011	For the Nine Months Ended September 30, 2010
Expected life	6.5 years	5-10 years
Expected volatility	70.54-76.32%	61-67%
Risk-free interest rate	1.38-3.34%	2.26-3.56%
Dividend yield	0%	0%

The expected life of the options is based upon the expected time to full-vesting and term of the options. The expected volatility assumptions are determined based upon the historical volatility of the Company’s daily

closing stock price. The risk-free interest rate is based on the continuous rates provided by the U.S. Treasury with a term equal to the expected life of the option. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

At September 30, 2011, stock options to purchase 2,126,804 shares of common stock at exercise prices ranging from $1.00 to $11.11 per share are outstanding and exercisable at various dates through 2021.

During the three months and nine months ended September 30, 2011, the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was $1.61 and $2.14, respectively. For the three month and nine month periods ended September 30, 2010, the weighted average fair value of options granted was $5.03 and $4.73, respectively. For the three month and nine month periods ended September 30, 2011 and for the three months ended September 30, 2010 no options were exercised. For the nine months ended September 30, 2010 the total intrinsic value of options exercised was $18.

The status of the Company's stock option plans at September 30, 2011 is summarized in the following table:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2010	2,132,879	$ 5.19	5.4	
Granted	496,050	3.18	9.6	
Exercised	—			
Forfeited or expired	(502,125)	6.59	—	
Outstanding at September 30, 2011	2,126,804	$ 4.39	6.5	$ 1,473
Vested and exercisable at September 30, 2011	874,041	$ 4.48	5.6	$ 644

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$1.00	48,952	1.2 years	$ 1.00	48,952	$ 1.00
$1.01-$4.50	1,635,202	7.2 years	$ 3.63	620,539	$ 3.67
$4.51-$11.11	442,650	4.5 years	$ 7.56	204,550	$ 7.79
$.01-$11.11	2,126,804	6.5 years	$ 4.39	874,041	$ 4.48

As of September 30, 2011, of the total 2,126,804 options outstanding, 1,252,763 have not vested. Of this total unvested amount, 914,438 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 1.9 years

As of September 30, 2011, of the $1,046 total unrecognized non-cash compensation cost related to unvested options, $661 is to be recognized over a period to be determined by performance-based milestones, and $385 is to be recognized over the requisite service period through 2015.

As of September 30, 2011, there were 1,629,264 shares available for future grants under the Company's 2005 Plan.

6. COMMITMENTS, CONTINGENCIES AND LITIGATION

The Company is obligated under a non-cancelable operating lease for office, lab, and assembly space expiring December 2016. The lease is subject to escalations for increases in operating expenses. The approximate aggregate minimum future payments due under this lease at September 30, 2011 are as follows:

2011 Remaining three months	$ 95
2012	410
2013	439
2014	456
2015	455
2016	456
	$ 2,311

Rental payments are recognized as rent expense on a straight-line basis over the term of the lease.

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

The Company, primarily through ASKION, engages Carl Zeiss Jena GmbH ("Zeiss") to build the lenses and assemblies, as well as provide certain technical consulting, for the MelaFind® units used in the Company's pivotal clinical trials and additional units being manufactured. This work is expected to continue for MelaFind® units through 2012.

In April, 2011, the Company entered into a "Last Time Buy" supply agreement with Arrow Electronics, Inc. ("Arrow"), a distributor for ON Semiconductors ("ON"), pursuant to which the Company agreed to purchase complementary metal-oxide-semiconductor ("CMOS") sensors. The CMOS sensor is a critical part of the Company's MelaFind® system. The Company believes that these CMOS sensors will be sufficient to meet the Company's needs until an alternative is found.

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 2011.

On November 19, 2010, a purported securities class action complaint was filed in the U.S. District Court for the Southern District of New York, naming as defendants the Company and certain of its officers and directors, entitled *Randall J. Pederson, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman*, No. 7:10-cv-08774-JFM. Two similar complaints were also filed, one on December 2, 2010 and the other on January 20, 2011, in the same District Court, entitled *Amy Steigman, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman*, No. 7:10-cv-09024-JFM; and *Martin Slove and Linda Slove, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman*, No. 1:11-cv-00429-JFM. These three securities class actions were consolidated into one action on February 15, 2011, entitled *In re MELA Sciences, Inc. Securities Litigation*, No. 10-Civ-8774-JFM ("securities class action"). The securities class action plaintiffs assert violations of the Securities Exchange Act of 1934, alleging, among other things, that defendants made misstatements and omissions regarding the Company's product, MelaFind®, and its prospects for FDA approval, on behalf of stockholders who purchased the Company's common stock during the period from February 13, 2009 through November 16, 2010, and seek unspecified damages. On May 2, 2011, the securities class action plaintiffs filed their amended consolidated complaint, alleging similar claims to their prior complaints. On July 29, 2011, defendents filed a motion to dismiss the consolidated amended complaint in its entirety. Plaintiff's opposition to the motion to dismiss was filed on September 23, 2011. In light of the Company's receipt of the Approvable Letter from the FDA for the MelaFind® PMA Application on September 22, 2011, the parties filed a stipulation on October 19, 2011 in which Plaintiff stated its intention to file a motion seeking leave to amend its complaint. Defendants withdrew the outstanding motion to dismiss the current Amended Complaint without prejudice to renew it at a later date.

The Company believes that it has meritorious defenses and intends to vigorously defend against the securities class action; however, as with any litigation, we cannot predict with certainty the eventual outcome of this litigation. An adverse outcome could have a material adverse effect on our business and our business could be materially harmed.

From time to time, we may be a party to certain legal proceedings, incidental to the normal course of our business. These may include controversies relating to contract claims and employment related matters, some of which claims may be material, in which case, we will make separate disclosure as required.

7. 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 this warrant, 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.

However, the Company is not obligated to make payments in excess of 10% of the aggregate purchase price of the common shares. The Company has concluded that it is unlikely that the Company would be required to remit any payments to its investors for failing to maintain its effectiveness. The Company's resale registration statements on Form S-3 were declared effective by the SEC 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). The shelf registration statement expired on July 7, 2011.

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.

The Company did not sell any stock to Kingsbridge Capital Limited under the CEFF in the nine months ended September 30, 2011. 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.

As of September 30, 2011, 1,095,315 shares of common stock remain available for sale under the CEFF, exclusive of the 200,000 outstanding warrants held by Kingsbridge. 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. 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 SEC on June 30, 2010, in connection with a takedown from the Company's effective shelf registration statement that closed on July 6, 2010. 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 offering expenses, net proceeds were approximately $15.2 million. Approximately $58.5 million remains available under the Company's 2010 shelf registration statement as of September 30, 2011.

As of September 30, 2011, the Company had 45,000,000 shares of $0.001 par value common stock authorized and 25,262,538 shares issued and outstanding; and 10,000,000 shares of $0.10 par value preferred stock authorized with no preferred shares issued and outstanding.

8. WARRANTS

The status of the Company's warrants at September 30, 2011 is summarized as follows:

	2007	2009	Total
Outstanding at December 31, 2010	346,781	200,000	546,781
Exercised	—	—	—
Forfeited	—	—	—
Expired	—	—	—
Outstanding at September 30, 2011	346,781	200,000	546,781

As previously discussed in connection with the Company's private placement in August 2007 the Company issued warrants to purchase up to 500,041 shares of the Company's common stock. At September 30, 2011, there were 346,781 of the 2007 warrants 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. This 200,000 share warrant is outstanding at September 30, 2011.

No warrants were exercised during the three and nine month periods ended September 30, 2011 and the three month period ended September 30, 2010. During the nine months ended September 30, 2010, warrants for the purchase of 263,549 shares of the Company's common stock were exercised for total proceeds of approximately $1.7 million.

9. 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 incurred and paid, pursuant to this consulting agreement, $6 in each of the three month periods ended September 30, 2011 and 2010 and $18 in each of the nine month periods ended September 30, 2011 and 2010. This consulting agreement is terminable by either party by providing thirty days' prior written notice.

Consulting Agreement with Gerald Wagner, Ph.D

In January 2007, Dr. Wagner, Ph.D., a member of the Company's Board of Directors, 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 in each of the three month periods ended September 30, 2011 and 2010 and $22.5 in each of the nine month periods ended September 30, 2011 and 2010.

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 September 2012, 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 $2 and $10 in the three month periods ended September 30, 2011 and September 30, 2010, respectively. The Company incurred consulting costs pursuant to this agreement of $8 and $45 in the nine month periods ended September 30, 2011 and September 30, 2010, respectively

10. OTHER INCOME

During April 2005, the Company discontinued all operations associated with its DIFOTI® product in order to focus its resources and attention on the development and commercialization of MelaFind®. 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®. Since July 2008, KaVo has been 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, 2011, the Company earned royalty income of $5 and $15, respectively. For the three and nine months ended September 30, 2010, the Company was paid royalty income of $5 and $15, respectively.

11. COMPREHENSIVE LOSS

For the three and nine month periods ended September 30, 2011 and 2010 respectively, the Company's comprehensive loss equaled its net loss.

12. SUBSEQUENT EVENTS

On November 1, 2011, the Company received written approval from the U.S. Food and Drug Administration of the Company's MelaFind® Pre-Market Approval application**.**

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, 2010.

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", "assuming", "expect", "intend", "plan", "will", "may", "should", "estimate", "predict", "potential", "continue", "contemplate" 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 and in our annual report on Form 10-K. We disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the period covered by this report or otherwise.

Overview

We are a medical device company focused on the design, development and commercialization of a non-invasive, point-of-care instrument to aid in the detection of early melanoma. Our flagship product, MelaFind®, features a hand-held imaging device that emits light of multiple wavelengths to capture images of suspicious pigmented skin lesions and extract data.

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, 2011, we had an accumulated deficit of approximately $115 million. We expect to continue to spend significant amounts on the development and commercialization of MelaFind®.

On November 1, 2011, the Company received written approval from the U.S. Food and Drug Administration of the Company's MelaFind® Pre-Market Approval application.

The MelaFind® PMA was submitted to the FDA in June 2009, and had been granted expedited review by the FDA. A pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a binding Protocol Agreement; all study end points were met. The results of the pivotal study were published in the *Archives of Dermatology* in October 2010 (on-line) and February 2011 (print). The PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel ("Panel") in November of 2010. The Panel voted favorably on all three questions posed by the FDA.

In February 2011, the Company submitted a PMA amendment containing a revised 'indications for use' statement limiting MelaFind® to use by dermatologists, based on discussions that ensued during the Panel meeting. In May 2011, the Company filed a second PMA amendment containing a training program for clinicians, an outline of which was presented at the Panel meeting. Also in May 2011, the Company submitted a Citizen's Petition to the FDA requesting that the Commissioner of the FDA enforce the binding Protocol Agreement, as well as FDA laws and regulations, in completing the review of the MelaFind® PMA.

The Company received an Approvable Letter from the FDA for the MelaFind® PMA application on September 22, 2011. Subsequent to September 30, 2011, the Company received an Approval Letter from the FDA on November 1, 2011 approving the MelaFind® PMA application. Based upon receipt of FDA approval of the MelaFind® PMA application, the Company withdrew its Citizen's Petition filed with the FDA in May 2011.

With FDA approval received, the Company plans to launch MelaFind® commercially in the United States during the first quarter of 2012.

In August of 2011, the Company received ISO 13485 certification of the Company's comprehensive management system for the design and manufacture of medical devices. On September 6, 2011, the Company received CE Mark approval for MelaFind®. With CE Mark approval, the Company has the ability to market MelaFind® to dermatologists across the European Union and in certain other countries.

The Company plans to launch MelaFind® commercially in Germany during the first quarter of 2012.

Our revenue for the foreseeable future will depend on the acceptance of MelaFind® by dermatologists in the U.S. and Europe and the progress of the planned controlled product launch. Revenue 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 (in thousands)

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). The shelf registration statement expired on July 7, 2011.

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 an aggregate Black Scholes fair value of $678. The issuance of this warrant was deemed to be a cost of the offering.

The Company did not sell any stock to Kingsbridge under the CEFF in the nine months ended September 30, 2011. 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 the 2010 sales were approximately $3.727 million.

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. 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 SEC on June 30, 2010, in connection with a takedown from the Company's effective shelf registration statement that closed on July 6, 2010. 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 offering expenses, net proceeds were approximately $15.2 million. Approximately $58.5 million remains available under the Company's 2010 shelf registration statement as of September 30, 2011.

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, 2011, the Company's total of cash and cash equivalents was approximately $17.0 million. Management believes that with FDA and CE mark approval this cash balance will be sufficient to fund the Company's controlled launches in the northeast U.S. and Germany and the anticipated level of operations for at least the next twelve months. However, the Company will require additional funds to achieve significant commercialization of MelaFind®. 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.

Our cash and cash equivalents at September 30, 2011 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

Net cash used in operations was $13,463 for the nine months ended September 30, 2011. For the corresponding period in 2010, net cash used in operations was $13,583. In both periods, cash used in operations was attributable to net losses after an adjustment for non-cash charges related to depreciation/amortization and share-based compensation, and other changes in operating assets and liabilities.

Cash Flows from Investing Activities

For the nine months ended September 30, 2011, there was $59 net cash used in our investing activities for the purchase of fixed assets. For the corresponding period in 2010, $1,051 net cash was used in our investing activities for the purchase of fixed assets.

Cash Flows from Financing Activities

For the nine months ended September 30, 2011, no net cash was provided by or used in our financing activities. For the nine months ended September 30, 2010, net cash provided by our financing activities was $20,717, representing proceeds from the July 2010 public offering, the Committed Equity Financing Facility, as well as the exercise of options and warrants.

Operating Capital and Capital Expenditure Requirements

We face certain risks and uncertainties, which are present in many emerging medical device companies. At September 30, 2011, we had an accumulated deficit of $115 million. 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 corporate infrastructure, and prepare for the commercial launch of MelaFind® in the first quarter of 2012.

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®, 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 future clinical trials;
- The success of our research and development efforts;
- The costs associated with maintaining regulatory approval;
- Reimbursement amounts for the use of MelaFind® that we are able to obtain from Medicare and third party payers;
- The amount of direct payments we are able to obtain from patients and/or physicians utilizing MelaFind®;
- The cost of commercialization activities, including product marketing and building a domestic direct sales force;
- The emergence of competing or complementary technological developments;
- The costs of filing, prosecuting, defending and enforcing any patent claims and other rights;
- The costs involved in defending any patent infringement actions or other litigation claims brought against us by third parties;
- The costs of maintaining or potentially building our inventory and other manufacturing expenses; 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, 2011, and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Operating leases	$ 2,311	$ 403	$ 884	$ 910	$ 114

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 space expires in December 2016.

Purchase Obligations (in thousands)

In April, 2011, the Company entered into a “Last Time Buy” supply agreement with Arrow Electronics, Inc. (“Arrow”), a distributor for ON Semiconductors (“ON”), pursuant to which the Company agreed to purchase complementary metal-oxide-semiconductor (“CMOS”) sensors. As of September 30, 2011, the Company is obligated to pay approximately $65, net per month for the next 12 months.

Results of Operations (in thousands)

Through the first nine months of 2011, the Company actively supported the FDA’s PMA review process leading to the receipt of an approval letter from the FDA on November 1, 2011, continued its efforts in Europe leading to receipt of the CE marking of MelaFind®, continued to develop procedures and equipment to allow for the efficient manufacture of MelaFind®, and intensified pre-commercialization activities in preparation for product launch.

Three Months Ended September 30, 2011 Compared to Three Months Ended September 30, 2010

Research and Development Expense

Research and development (“R&D”) expenses experienced an overall decrease of $499 or 17% in the three months ended September 30, 2011, as compared to the corresponding three month period a year earlier. With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, approval of the PMA application by the FDA was deemed probable by the Company and $355 in non-cash compensation expense was recorded to R&D as of September 30, 2011 for options which related to FDA approval-based performance milestones. Within R&D, offsetting expense decreases were primarily in development costs at Askion which decreased $549 as we move toward commercialization, U.S. research and development with a $95 decrease in design subcontracting and product improvements, clinical studies costs which decreased $97 and software development which had $80 less in compensation costs.

General and Administrative Expense

General and Administrative (“G&A”) expenses experienced an overall increase of $1,657 or 81% for the three months ended September 30, 2011, as compared to the corresponding three month period a year earlier. With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, approval of the PMA application by the FDA was deemed probable by the Company and $1,534 in non-cash compensation expense was recorded to G&A as of September 30, 2011 for options which related to FDA approval-based performance milestones. Also within G&A, corporate consulting and professional fees increased by $135 from the 2010 level reflecting activity associated with the continued review of the MelaFind® PMA application along with work associated with legal actions brought against certain officers and directors of the Company.

Interest Income

Interest income for the three months ended September 30, 2011 increased to $11from $10 in the comparable period of 2010. Interest income increased as a reflection of the improvement in interest rates obtained on our cash balances.

Other Income

Other income remained essentially the same in 2011 from a year earlier.

Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010

Research and Development Expense

Research and development expenses experienced an overall decrease of $642 or 8% in the nine months ended September 30, 2011, as compared to the corresponding nine month period a year earlier. With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, approval of the PMA application by the FDA was deemed probable by the Company and $355 in non-cash compensation expense was recorded to R&D as of September 30, 2011 for options which related to FDA approval-based performance milestones. Within R&D, offsetting expense decreases were primarily in development costs at Askion which decreased $678 and U.S. research

and development with a $150 decrease in design sub-contracting and a $143 decrease in product improvement materials.

General and Administrative Expense

General and Administrative ("G&A") expenses experienced an overall increase of $1,939 or 31% for the nine months ended September 30, 2011, as compared to the corresponding nine month period a year earlier. With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, approval of the PMA application by the FDA was deemed probable by the Company and $1,534 in non-cash compenstion expense was recorded as of September 30, 2011 for options which related to FDA approval-based performance milestones. Also within G&A, corporate consulting, professional fees and investor relations increased by $656 and legal fees increased by $196 from the 2010 level reflecting activity associated with the continued review of the MelaFind® PMA application along with work associated with legal actions brought against certain officers and directors of the Company. These increases were partially offset by a $254 decrease in market research and reimbursement consulting and a $191 decrease in office and computer supplies and maintenance costs.

Interest Income

Interest income for the nine months ended September 30, 2011 increased to $45 from $14 in the comparable period of 2010. Interest income increased as a reflection of the improvement in interest rates obtained on our cash balances.

Other Income

Other income remained essentially the same in 2011 from a year earlier.

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 have not launched any commercialized products or have any significant source of revenue.

Stock-Based Compensation

The Company records compensation expense associated with stock options and other forms of equity compensation.

The Company grants to certain employees stock options that vest over a requisite service period or with the attainment of performance milestones over which the Company has control of the timing required to satisfy. A compensation charge is recorded over the service period or the probable period estimated to satisfy the performance condition. The probability of vesting is updated at each reporting period and compensation is adjusted prospectively.

The Company also grants to certain employees stock options that vest with the attainment of performance milestones over which the Company has no control of the timing required to satisfy. Upon the attainment of these performance milestones, there will be a significant compensation charge based on the fair value of such options on the date granted. With the receipt of the PMA Approvable Letter from the FDA on September 22, 2011, the Company deemed it probable that it would subsequently receive PMA approval from the FDA. Accordingly, $1,889 in non-cash compensation expense was recorded as of September 30, 2011 representing options on which the performance vesting milestone is related to FDA approval.

The Company accounts for non-employee stock-based awards in which goods or services are the consideration received for the equity instruments issued based on the fair value of the equity instruments issued.

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 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

None

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, 2011, 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 l0-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, 2011 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

On November 19, 2010, a purported securities class action complaint was filed in the U.S. District Court for the Southern District of New York, naming as defendants the Company and certain of its officers and directors, entitled *Randall J. Pederson, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman*, No. 7:10-cv-08774-JFM. Two similar complaints were also filed, one on December 2, 2010 and the other on January 20, 2011, in the same District Court, entitled *Amy Steigman, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman*, No. 7:10-cv-09024-JFM; and *Martin Slove and Linda Slove, Individually and on Behalf of All Others Similarly Situated v. MELA Sciences, Inc., Joseph V. Gulfo, Richard I. Steinhart, and Breaux Castleman*, No. 1:11-cv-00429-JFM. These three securities class actions were consolidated into one action on February 15, 2011, entitled *In re MELA Sciences, Inc. Securities Litigation*, No. 10-Civ-8774-JFM ("securities class action"). The securities class action plaintiffs assert violations of the Securities Exchange Act of 1934, alleging, among other things, that defendants made misstatements and omissions regarding the Company's product, MelaFind®, and its prospects for FDA approval, on behalf of stockholders who purchased the Company's common stock during the period from February 13, 2009 through November 16, 2010, and seek unspecified damages. On May 2, 2011, the securities class action plaintiffs filed their amended consolidated complaint, alleging similar claims to their prior complaints. On July 29, 2011, defendents filed a motion to dismiss the consolidated amended complaint in its entirety. Plaintiff's opposition to the motion to dismiss was filed on September 23, 2011. In light of the Company's receipt of the Approvable Letter from the FDA for the MelaFind® PMA Application on September 22, 2011, the parties filed a stipulation on October 19, 2011 in which Plaintiff stated its intention to file a motion seeking leave to amend its complaint. Defendants withdrew the outstanding motion to dismiss the current Amended Complaint without prejudice to renew it at a later date.

The Company believes that it has meritorious defenses and intends to vigorously defend against the securities class action; however, as with any litigation, we cannot predict with certainty the eventual outcome of this litigation. An adverse outcome could have a material adverse effect on our business and our business could be materially harmed.

From time to time, we may be a party to certain legal proceedings, incidental to the normal course of our business. These may include controversies relating to contract claims and employment related matters, some of which claims may be material, in which case, we will make separate disclosure as required.

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, 2010. In addition, the following risk factors have materially changed during the nine months ended September 30, 2011:

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 nine months ended September 30, 2011 was approximately $15.9 million and as of September 30, 2011, we had an accumulated deficit of approximately $115 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind®. In the process of fully commercializing MelaFind® , we expect to incur significant sales, marketing, and manufacturing expenses, which will require additional funding. 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 will not be able to achieve significant commercialization of MelaFind® without additional funding, and may be unable to complete the development and commence commercialization of other products without additional funding.

As of September 30, 2011 we had approximately $17.0 million in cash and cash equivalents. Our operations have consumed substantial amounts of cash for each of the last nine years. We expect to continue to spend substantial amounts on research and development and we expect that our cash used by operations will increase significantly in each of the next several years. We will need additional funds to achieve significant commercialization of MelaFind®, including development of a direct sales force and expansion of manufacturing capacity. Any additional equity 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 future clinical trials;
- the success of our research and development efforts;
- the costs of maintaining regulatory approval;
- reimbursement amounts for the use of MelaFind® that we are able to obtain from Medicare and third party payers;

- the cost of commercialization activities, including product marketing and building a domestic direct sales force;
- the amount of direct payments we are able to obtain from patients or physicians utilizing MelaFind®;
- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other rights;
- the costs involved in defending any patent infringement actions or other litigation claims brought against us by third parties;
- the costs of maintaining inventory and other manufacturing expenses; 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

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

None

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. [Reserved]

Item 5. Other Information

(a) Not applicable

(b) Not applicable

Item 6. Exhibits

Exhibit Number	Exhibit Title
31.1#	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2#	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1#	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.1#	Interactive Data File
#	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 4, 2011

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.
101.1	Interactive Data File

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 4, 2011

/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 4, 2011

/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, 2011 (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 4,, 2011

/s/ Richard I. Steinhart
Richard I. Steinhart
Vice President & Chief Financial Officer
(Principal Accounting and Financial Officer)
November 4, 2011

* 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.