# 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 June 30, 2011

to

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

For the transition period from

Commission file number 000 — 51481

### 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

**10533** (Zip Code)

(Address of Principal Executive offices)

### 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 ☑ 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

Smaller reporting company o

(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 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 July 29, 2011: 25,262,538 shares of the Registrant's common stock were outstanding.

#### MELA Sciences, Inc. Table of Contents

PART I. FINANCIAL INFORMATION	Page
ITEM 1. Financial Statements	
Condensed Balance Sheets as of June 30, 2011 (unaudited) and December 31, 2010	2
Condensed Statements of Operations (unaudited) for the three and six month periods ended June 30, 2011 and 2010	3
Condensed Statements of Cash Flows (unaudited) for the six month period ended June 30, 2011 and 2010	4
Notes to Condensed Financial Statements (unaudited)	5
ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	14
ITEM 3. Quantitative and Qualitative Disclosures about Market Risk	21
ITEM 4. Controls and Procedures	21
PART II. OTHER INFORMATION	
ITEM 1. Legal Proceedings	21
ITEM 1A. Risk Factors	22
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds	23
ITEM 3. Defaults Upon Senior Securities	23
ITEM 4. [Reserved]	23
ITEM 5. Other Information	23
ITEM 6. Exhibits	24
<u>SIGNATURES</u>	25
EXHIBIT INDEX EX-10.1	26
EX-31.1 EX-31.2 EX-32.1 EX-101 INSTANCE DOCUMENT EX-101 SCHEMA DOCUMENT EX-101 CALCULATION LINKBASE DOCUMENT EX-101 LABELS LINKBASE DOCUMENT EX-101 PRESENTATION LINKBASE DOCUMENT	
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## MELA SCIENCES, INC. CONDENSED BALANCE SHEETS

	June 30, 	December 31, 2010 *
ASSETS	(unauancu)	
Current Assets:		
Cash and cash equivalents	\$ 20,942,709	\$ 30,520,812
Prepaid expenses and other current assets	934,029	523,672
Total Current Assets	21,876,738	31,044,484
Property and equipment, net	1,826,578	2,073,602
Patents and trademarks, net	65,158	71,108
Deferred financing costs	62,391	62,391
Other assets	337,705	337,705
Total Assets	\$ 24,168,570	\$ 33,589,290
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 645,643	\$ 1,096,505
Accrued expenses (includes related parties of \$34,000 as of June 30, 2011)	591,312	559,975
Other current liabilities	28,891	29,538
Total Current Liabilities	1,265,846	1,686,018
Long Term Liabilities:		
Deferred rent	121,260	104,304
Total Long Term Liabilities	121,260	104,304
Total Liabilities	1,387,106	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		
June 30, 2011 and December 31, 2010	25,263	25,263
Additional paid-in capital	131,650,548	130,916,326
Accumulated deficit	(108,894,347)	(99,142,621)
Total Stockholders' Equity	22,781,464	31,798,968
Total Liabilities and Stockholders' Equity	\$ 24,168,570	\$ 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 June 30,		Six months er	
	2011	2010	2011	2010
Operating expenses:				
Research and development	\$ 2,620,554	\$ 2,552,689	\$ 5,196,682	\$ 5,339,759
General and administrative	2,208,059	2,048,157	4,601,179	4,319,322
Operating loss	(4,828,613)	(4,600,846)	(9,797,861)	(9,659,081)
Interest income	13,934	3,009	34,465	3,961
Other income, net	5,022	4,999	11,670	12,497
Gain on sale of fixed assets	_	1,500	_	27
Net loss	\$ (4,809,657)	\$ (4,591,338)	\$ (9,751,726)	\$ (9,642,596)
Basic and diluted net loss per common share	\$ (0.19)	\$ (0.20)	\$ (0.39)	\$ (0.42)
		·	·	
Basic and diluted weighted average number of common shares				
outstanding	25,262,538	23,028,854	25,262,538	22,886,964

See accompanying notes to the financial statements

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

	Six Months Ended June 30	
Cash flows from operating activities:		2010
Net loss	\$ (9,751,726)	\$ (9,642,596)
Adjustments to reconcile net loss to net cash used in operating activities:	Ψ (0,7 01,7 20)	Ψ (5,012,550)
Depreciation and amortization	283,785	253,492
Noncash compensation	734,222	366,382
Changes in operating assets and liabilities:	- ,	
(Increase) decrease in prepaid expenses and other current assets	(410,357)	322,685
Decrease in accounts payable and accrued expenses	(419,525)	(124,669)
Increase in other assets	`	(273,220)
Increase in deferred rent	16,956	52,152
Decrease in other current liabilities	(647)	(8,484)
Net cash used in operating activities	(9,547,292)	(9,054,258)
Cash flows from investing activities:		
Purchases of property and equipment	(30,811)	(637,014)
Proceeds from sale of fixed assets	_	1,473
Net cash used in investing activities	(30,811)	(635,541)
Cash flows from financing activities:		
Proceeds from exercise of stock options	_	26,070
Proceeds from exercise of stock warrants	_	1,691,633
Expenses related to public offering	_	(130,086)
Proceeds from Committed Equity Financing Facility	_	3,750,000
Expenses related to Committed Equity Financing Facility	<u></u>	(6,717)
Net cash provided by financing activities	<del>-</del>	5,330,900
Net decrease in cash and cash equivalents	(9,578,103)	(4,358,899)
Cash and cash equivalents at beginning of period	30,520,812	29,673,420
Cash and cash equivalents at end of period	\$20,942,709	\$25,314,521
Supplemental Schedule of Non-cash Investing and Financing Activities		
Deferred financing costs charged to additional paid-in capital	<u> </u>	\$ 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.

The MelaFind® Pre-Market Approval ("PMA") application was submitted in June 2009 and is under review at the U.S. Food and Drug Administration ("FDA"). A pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a Protocol Agreement. In addition, the MelaFind® PMA has been granted expedited review by the FDA.

On November 18, 2010, the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel ("Panel"). The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on 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. Also, on May 12, 2011, the Company submitted a second PMA amendment containing a training program for clinicians, an outline of which was presented at the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendments. On May 9, 2011, the Company filed a Citizen's Petition with the FDA requesting the Commissioner of the FDA to enforce the binding Protocol Agreement, as well as FDA laws and regulations, in completing the review of the MelaFind® PMA.

Upon obtaining approval from the FDA, we plan to launch MelaFind® commercially in the United States.

Also, in the first six months of 2011, the Company continued the process, initiated in 2010, toward being able to introduce the MelaFind® device commercially in Europe. The Company is actively planning representation, conducting market research activities and working with European regulatory agencies on achieving Conformite Europeanne ("CE") marking of MelaFind®.

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 June 30, 2011, the Company's total of cash and cash equivalents was approximately \$20.9 million. Management believes that this cash balance will be sufficient to fund the Company's 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.

#### 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:

	June	30,
	2011	2010
Common stock options	2,107,429	2,164,598
Common stock warrants	546,781	614,906
Total	2,654,210	2,779,504

#### 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 compensation expense recognized in the Statement of Operations in the second quarter of 2011 and 2010 for stock options amounted to \$564 (of which \$13 relates to performance milestones) and \$184 (of which \$6 relates to performance milestones), respectively. For the six months ended June 30, 2011 and 2010, compensation expense for stock options amounted to \$734 (of which \$28 relates to performance milestones) and \$366 (of which \$11 relates to performance milestones), respectively. Cash received from options and warrants exercised under all share-based payment arrangements for the three month periods ended June 30, 2011 and 2010 were \$0 and \$20, respectively, and for the six month periods ended June 30, 2011 and 2010 were \$0 and \$1,717 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 Six Months Ended June 30, 2011	Ended June 30, 2010
Expected life	6.5 years	5-10 years
Expected volatility	70.54-76.32%	61%
Risk-free interest rate	2.47-3.34%	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 June 30, 2011, stock options to purchase 2,107,429 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 six months ended June 30, 2011, the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was \$2.18 and \$2.20, respectively. For the three month and six month periods ended June 30, 2010, the weighted average fair value of options granted was \$4.61 and \$4.68, respectively. For the three month and six month periods ended June 30, 2011 no options were exercised and for the three months and six months ended June 30, 2010 the total intrinsic value of options exercised was \$11 and \$18, respectively.

The status of the Company's stock option plans at June 30, 2011 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, 2010	2,132,879	\$5.19	5.4	
Granted	439,800	3.27	9.8	
Exercised	_			
Forfeited or expired	(465,250)	6.59	_	
Outstanding at June 30, 2011	2,107,429	\$4.48	6.6	\$66
Vested and exercisable at June 30, 2011	850,791	\$4.53	5.6	\$66

	Options Outstanding						
	Weighted-			Options Exe	Options Exercisable		
		Average	Weighted		Weighted-		
		Remaining	Average		Average		
	Number	Contractual	Exercise	Number	Exercise		
Range of Exercise Prices	Outstanding	Life	Price	Exercisable	Price		
\$.01-\$1.00	48,952	1.4 years	\$1.00	48,952	\$1.00		
\$1.01-\$4.50	1,578,952	7.4 years	\$3.68	591,789	\$3.70		
\$4.51-\$11.11	479,525	4.5 years	\$7.48	210,050	\$7.71		
\$.01-\$11.11	2,107,429	6.6 years	\$4.48	850,791	\$4.53		

As of June 30, 2011, of the total 2,107,429 options outstanding, 1,256,638 have not vested. Of this total unvested amount, 931,813 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 1.9 years

As of June 30, 2011, of the \$3,186 total unrecognized compensation cost related to unvested options, \$2,708 is to be recognized over a period to be determined by performance-based milestones, and \$478 is to be recognized over the requisite service period through 2015.

As of June 30 2011, there were 1,648,639 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 June 30, 2011 are as follows:

2011 Remaining six months	\$ 191
2012	410
2013	439
2014 2015 2016	456
2015	455
2016	456
	\$ 2,407

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 additional 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. A downpayment of \$500 was made on this purchase during the three months ended June 30, 2011. 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 complaint, alleging similar claims to their prior complaints. On July 29, 2011, Defendants filed a motion to dismiss the consolidated amended complaint in its entirety. Plaintiff's opposition to the motion to dismiss is due on September 15, 2011.

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). Approximately \$13.1 million remained available under the Company's 2008 shelf registration statement as of June 30, 2011; however, the shelf registration statement subsequently 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 six months ended June 30, 2011. Under the CEFF, during the six month period ending June 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 June 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 June 30, 2011.

As of June 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 June 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 June 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 June 30, 2011, 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. This 200,000 share warrant is outstanding at June 30, 2011.

No warrants were exercised during the three and six month periods ended June 30, 2011 and the three month period ended June 30, 2010. During the six months ended June 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 June 30, 2011 and 2010 and \$12 in each of the six month periods ended June 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 June 30, 2011 and 2010 and \$15 in each of the six month periods ended June 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 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 \$0 and \$12 in the three month periods ended June 30, 2011 and June 30, 2010, respectively. The Company incurred consulting costs pursuant to this agreement of \$6 and \$35 in the six month periods ended June 30, 2011 and June 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 six months ended June 30, 2011, the Company earned royalty income of \$5 and \$10, respectively. For the three and six months ended June 30, 2010, the Company was paid royalty income of \$5 and \$10, respectively.

#### 11. COMPREHENSIVE LOSS

For the three and six month periods ended June 30, 2011 and 2010 respectively, the Company's comprehensive loss equalled net loss.

#### 12. SUBSEQUENT EVENTS

None

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 whether the data from our pre-clinical studies and clinical trials is sufficient to support regulatory approval of Melafind®, whether we are required to provide the FDA with additional data or perform additional testing on MelaFind® or, even if we do receive regulatory approval, whether any such approval is for the indications we seek. Additional factors 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 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 June 30, 2011, we had an accumulated deficit of \$108.9 million. We expect to continue to spend significant amounts on the development of MelaFind®.

The MelaFind® Pre-Market Approval ("PMA") application was submitted in June 2009 and is under review at the U.S. Food and Drug Administration ("FDA"). A pivotal trial conducted to establish the safety and effectiveness of MelaFind® was performed under the auspices of a Protocol Agreement. In addition, the MelaFind® PMA has been granted expedited review by the FDA.

On November 18, 2010, the Company's PMA application for MelaFind® was reviewed by the FDA's General and Plastic Surgery Devices Panel ("Panel"). The Panel voted favorably on all three questions instructed by the FDA. The FDA advisory Panel vote is non-binding on 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. Also, on May 12, 2011, the Company submitted a second PMA amendment containing a training program for clinicians, an outline of which was presented at the Panel meeting. The Company has requested a meeting with the FDA to review the Panel outcome as well as the Company's PMA and PMA amendments. On May 9, 2011, the Company filed a Citizen's Petition with the FDA requesting the Commissioner of the FDA to enforce the binding Protocol Agreement, as well as FDA laws and regulations, in completing the review of the MelaFind® PMA.

Upon obtaining approval from the FDA, we plan to launch MelaFind® commercially in the United States.

Also, in the first six months of 2011, the Company continued the process, initiated in 2010, toward being able to introduce the MelaFind® device commercially in Europe. The Company is actively planning representation, conducting market research activities and working with European regulatory agencies on achieving Conformite Europeanne ("CE") marking of MelaFind®.

Our revenue for the foreseeable future will depend on the approval of MelaFind® by the FDA and /or European regulatory agencies and the commercialization of MelaFind®, 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 (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). Approximately \$13.1 million remained available under the Company's 2008 shelf registration statement as of June 30, 2011; however, the shelf registration statement subsequently 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 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 under the CEFF in the six months ended June 30, 2011. Under the CEFF, during the six month period ended June 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 June 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 June 30, 2011, the Company's total of cash and cash equivalents was approximately \$20.9 million. Management believes that this cash balance will be sufficient to fund the Company's 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 June 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 \$9,547 for the six months ended June 30, 2011. For the corresponding period in 2010, net cash used in operations was \$9,054. 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 six months ended June 30, 2011, there was \$31 net cash used in our investing activities for the purchase of fixed assets. For the corresponding period in 2010, \$636 net cash was used in our investing activities, for the purchase of fixed assets.

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

For the six months ended June 30, 2011, no net cash was provided by or used in our financing activities. For the six months ended June 30, 2010, net cash provided by our financing activities was \$5,331, representing proceeds from 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 June 30, 2011, we had an accumulated deficit of \$108.9 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 pursue the regulatory approvals for MelaFind®, continue to develop the MelaFind® system, expand our corporate infrastructure, and prepare for the potential commercial launch of MelaFind®. We do not expect to generate significant product revenue until we are successful in obtaining PMA approval and/or CE Marking for MelaFind®.

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 clinical trials;
- The success of our research and development efforts;
- The costs and timing of regulatory approval;
- Reimbursement amounts for the use of MelaFind® that we are able to obtain from Medicare and third party 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 June 30, 2011, and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

		Less than			More than
	Total	1 year	1-3 years	4-5 years	5 years
Operating leases	\$2,407	\$396	\$872	\$911	\$228

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.

#### Results of Operations (in thousands)

Through the first six months of 2011, the Company actively supported the FDA's PMA review process, continued to develop procedures and equipment to allow for the efficient manufacture of MelaFind®, intensified pre-commercialization activities in preparation for product launch and continued its efforts to achieve CE marking of MelaFind® in Europe.

#### Three Months Ended June 30, 2011 Compared to Three Months Ended June 30, 2010

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

Research and development ("R&D") expenses experienced an overall increase of \$68 or 3% in the three months ended June 30, 2011, as compared to the corresponding three month period a year earlier. Within R&D non-cash compensation associated with stock option grants increased \$210, with the balance of R&D spending decreasing \$142. The decrease was primarily in US research and development expenses with decreases of \$113 in consulting and design subcontracting and \$27 in product improvement.

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

General and Administrative ("G&A") expenses experienced an overall increase of \$160 or 8% for the three months ended June 30, 2011, as compared to the corresponding three month period a year earlier. Non-cash compensation associated with stock option grants increased by \$170 in 2011 compared to 2010, with the balance of G&A spending decreasing \$10. Decreased costs experienced within G&A include a \$92 decrease in salaries and benefits, \$66 decrease in marketing consulting costs, a \$32 decrease in travel and living expenditures and facility costs which were lower by \$63. Corporate consulting and legal fees increased by \$257 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 June 30, 2011 increased to \$14 from \$3 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.

#### Six Months Ended June 30, 2011 Compared to Six Months Ended June 30, 2010

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

Research and development expenses experienced an overall decrease of \$143 or 3% in the six months ended June 30, 2011, as compared to the corresponding six month period a year earlier. Within R&D, non-cash compensation associated with stock option grants increased \$262, with the balance of R&D spending decreasing \$405. The decrease was primarily in US research and development with a \$280 decrease in consulting and design subcontracting and a \$117 decrease in product improvement. Development costs at Askion decreased \$109 and overall salaries and benefits within R&D increased by\$104.

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

General and Administrative ("G&A") expenses experienced an overall increase of \$282 or 7% for the six months ended June 30, 2011, as compared to the corresponding six month period a year earlier. Non-cash compensation associated with stock option grants increased by \$106 in 2011 compared to 2010, with the balance of G&A spending increasing \$176. Corporate consulting and legal fees increased by \$628 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. Decreased costs experienced within G&A include a \$68 decrease in salaries and benefits, \$248 decrease in marketing consulting, a \$112 decrease in office supplies, and facility costs which were lower by \$29.

#### Interest Income

Interest income for the six months ended June 30, 2011 increased to \$34 from \$4 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 do not have any commercialized products or any 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.

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 June 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 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 June 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, Defendants filed a motion to dismiss the consolidated amended complaint in its entirety. Plaintiff's opposition to the motion to dismiss is due on September 15, 2011.

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 six months ended June 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 six months ended June 30, 2011 was approximately \$9.8 million and as of June 30, 2011, we had an accumulated deficit of approximately \$108.9 million. Our research and development expenses may continue to increase in connection with our clinical trials and other development activities related to MelaFind®. Upon receiving PMA approval for MelaFind® from the FDA, 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 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 June 30, 2011 we had \$20.9 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. We will need additional funds to fully commercialize MelaFind®, including development of a direct sales force and expansion of manufacturing capacity. We expect that our cash used by operations will increase significantly in each of the next several years, and should we encounter any material delays or impediments, we may need additional funds to complete the development of MelaFind®, commence commercialization, and achieve significant commercialization of MelaFind®. 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 clinical trials;
- the success of our research and development efforts;
- the costs and timing of regulatory approval;
- reimbursement amounts for the use of MelaFind® that we are able to obtain from Medicare and third party 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 and/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
10.1#	Supply Agreement with Arrow Electronics, Inc., April 8, 2011*
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
*	Portions of this exhibit have been omitted pursuant to a request for confidential treatment.
	24

#### **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: August 5, 2011

#### EXHIBIT INDEX

Exhibit No.	Description
10.1	Supply Agreement with Arrow Electronics, Inc., April 8, 2011.*
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.

<sup>\*</sup> Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

ARROW ELECTRONICS, INC. NORTH AMERICAN COMPONENTS OPERATION 7459 SOUTH LIMA STREET ENGLEWOOD, CO 80112

April 8, 2011

Mr. Joseph V. Gulfo President & CEO, MELA Sciences, Inc. 50 South Buckhout Street, Suite 1 Irvington, NY 10533

Re: Letter of Understanding Regarding Proposed Terms of Sale

Dear Mr. Gulfo:

In consideration of the soon to be established credit limit of \$75.0K, and re-payment terms of net 30-days, MELA Sciences, Inc. and Arrow Electronics, Inc. agree to the following:

1. MELA Sciences will deposit \$500,000.00 USD into an escrow account, #\*\*\*, for the benefit of MELA, which will be held in trust, interest free, and be applied to the invoices described herein, and according to the attached payment schedule. This payment is to be made via a wire transfer of funds to Arrow's bank. That wire address being:

Bank Name: JP Morgan Chase Bank

Bank Address: 10410 Highland Manor Drive, Tampa, FL 33610

ABA Routing #: 021000021 SWIFT #: CHASUS33 Account #: \*\*\*

Bank Telephone No: 212-552-5729 Bank Contact Name: Max Toscano

- 2. With respect to the Last Time Buy Agreement (LTB), CYII4SM1300AA-QDC, MELA Sciences has with Cypress Semiconductor Corporation (who was recently acquired by On Semiconductor Corporation and who will honor the LTB Agreement between the parties), MELA will provide Arrow with a purchase order for \*\*\* Cypress components, specifically part number CYII4SM1300AA-QDC, with a per unit price of \$\*\*\* USD. The total value of these components is \$1,265,039.90 USD. After the trust deposit mentioned above is received, Arrow will acquire, from Cypress, the LTB components mentioned above after a Non-Cancelable, Non-Returnable (NCNR) contract is executed by MELA Sciences.
- 3. Arrow will be the facilitator by which components are returned, or credited, if the yield is not 90.0% as stated in section 5.1 of the Cypress Agreement. Pursuant to the LTB Agreement Cypress should replace, or credit, nonconforming goods in excess of the 10% agreed upon rate within 30 days following notice to Cypress from MELA Sciences regarding the same. Cypress will deliver replacement sensors to the MELA/Askion facility and will remit all credits to MELA Sciences through Arrow. Arrow shall credit MELA Sciences immediately following its receipt of any such

<sup>\*\*\*</sup> This material has been omitted pursuant to a request for confidential treatment filed separately with the Securities and Exchange Commission.

credit from Cypress.

- 4. MELA Sciences understands that there is a lead-time of approximately 20 weeks for Arrow to acquire the named components from Cypress. Arrow will promptly notify MELA Sciences once these components are available and ready for shipment. If there are unusual delays Arrow will promptly notify MELA Sciences.
- 5. Once the components are available for delivery MELA Sciences agrees to accept twelve (12) consecutive monthly shipments of \*\*\* pieces in accordance with the attached schedule, the first shipment to take place immediately.
- 6. Each of the twelve shipments will be booked with net 30-day terms, and each for \$105,420.00 USD, plus any applicable tax, freight and handling fees. Arrow will apply \$41,666.67 from the funds held in trust to each of the twelve invoices. MELA Sciences agrees to remit eleven (11) on-time payments of \$63,753.33 net-30 days, subject to any credit issued, and one (1) final on-time payment of \$63,753.23. At the same time MELA Sciences agrees to remit any applicable taxes, freight charges and handling fees with each of the twelve payments. See attached schedule.
- 7. If at any time MELA Sciences is unable to pay its obligation under this arrangement, Arrow reserves the right to use the balance of the trust deposit to satisfy the remaining obligation and to seek after any legal means available to it in order to satisfy the amount still owing. If for any reason Cypress notifies MELA Sciences, or Arrow, that it will no longer be providing the sensors contemplated hereby, or cannot do so within three (3) months of the delivery schedule attached hereto, then upon MELA Science's request Arrow shall promptly remit the remainder of any funds in the trust account held by it for MELA Sciences and this agreement shall terminate.

Please acknowledge your acceptance of the above by signing below and returning the original executed document to me at the above address.

Sincerel	ly,
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ARROW ELECTRONICS II	IINC.
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Michael Fassula, Account Finance Manager

Joseph V. Gulfo, President & CEO, MELA Sciences, Inc.

303-645-8705 Telephone	
/s/ Joseph V. Gulfo	April 8, 2011

\*\*\* This material has been omitted pursuant to a request for confidential treatment filed separately with the Securities and Exchange Commission.

Date

MELA Sciences, Inc. Shipment & Payment Schedule

Shipment Scheo	dule		Payment S	chedule
Month	Components Shipped To MELA	Parts Remaining To Be Shipped	Payment From Trust	MELA Sciences Pays*
1	0	0	\$ —	\$(500.000.00)
2	0	0	¢	¢`
2	· ·	•	<b>5</b> —	<b>5</b> —
3	0	0	<b>\$</b> —	<b>\$</b> —
4	0	0	<b>\$</b> —	<b>\$</b> —
5	***	***	\$ —	<b>\$</b>
6	***	***	\$41,666.67	\$ 63,753.33
7	***	***	\$41,666.67	\$ 63,753.33
8	***	***	\$41,666.67	\$ 63,753.33
9	***	***	\$41,666.67	\$ 63,753.33
10	***	***	\$41,666.67	\$ 63,753.33
11	***	***	\$41,666.67	\$ 63,753.33
12	***	***	\$41,666.67	\$ 63,753.33
13	***	***	\$41,666.67	\$ 63,753.33
14	***	***	\$41,666.67	\$ 63,753.33
15	***	***	\$41,666.67	\$ 63,753.33
16	***	0	\$41,666.67	\$ 63,753.33
17	0	0	\$41,666.67	\$ 63,753.33

<sup>\*</sup> Plus Applicable Taxes, Freight & Handling Charges

<sup>\*\*\*</sup> This material has been omitted pursuant to a request for confidential treatment filed separately with the Securities and Exchange Commission.

### 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: August 5, 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: August 5, 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 June 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) August 5, 2011

/s/ Richard I. Steinhart Richard I. Steinhart Vice President & Chief Financial Officer (Principal Accounting and Financial Officer) August 5, 2011

<sup>\*</sup> 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.