Table of Contents

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, 2012

☐ **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 ☒ ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

As of October 31, 2012, 31,604,138 shares of the Registrant's common stock were outstanding.

Table of Contents

MELA Sciences, Inc.
Table of Contents

MELA SCIENCES, INC.
CONDENSED BALANCE SHEETS

	September 30, 2012 (unaudited)	December 31, 2011 *
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,275,849	$ 27,996,871
Accounts receivable	100,578	—
Inventory	656,560	—
Prepaid expenses and other current assets	619,495	1,061,550
Total Current Assets	14,652,482	29,058,421
Property and equipment, net	5,243,082	1,626,791
Patents and trademarks, net	50,283	59,208
Deferred financing costs	—	62,391
Deferred public offering cost	122,291	—
Other assets	71,985	586,498
Total Assets	$ 20,140,123	$ 31,393,309
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable (includes related parties of $54,750 and $36,027- as of September 30, 2012 and December 31, 2011, respectively)	$ 1,277,540	$ 670,950
Accrued expenses	913,110	745,754
Deferred revenue	82,782	—
Other current liabilities	81,897	30,993
Total Current Liabilities	2,355,329	1,447,697
Long Term Liabilities:		
Deferred rent	142,383	138,216
Deferred revenue	68,094	—
Total Long Term Liabilities	210,477	138,216
Total Liabilities	2,565,806	1,585,913
COMMITMENTS, CONTINGENCIES and LITIGATION (Note 8)		
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 31,323,910 shares at September 30, 2012 and 30,307,538 at December 31, 2011	31,324	30,308
Additional paid-in capital	153,664,419	149,304,424
Accumulated deficit	(136,121,426)	(119,527,336)
Stockholders' Equity	17,574,317	29,807,396
Total Liabilities and Stockholders' Equity	$ 20,140,123	$ 31,393,309

* Derived from the audited balance sheet as of December 31, 2011

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,	
	2012	2011	2012	2011
Revenue	$ 69,127	$ —	$ 156,134	$ —
Cost of revenue	568,899	—	1,071,357	—
Gross profit	(499,772)	—	(915,223)	—
Operating expenses:				
Research and development	1,398,500	2,437,811	5,506,596	7,634,493
General and administrative	3,469,435	3,689,991	10,215,501	8,291,170
Operating loss	(5,367,707)	(6,127,802)	(16,637,320)	(15,925,663)
Interest income	5,875	10,729	28,280	45,194
Other income	4,954	6,419	14,950	18,089
Net loss	$ (5,356,878)	$ (6,110,654)	$(16,594,090)	$(15,862,380)
Basic and diluted net loss per common share	$ (0.17)	$ (0.24)	$ (0.55)	$ (0.63)
Basic and diluted weighted average number of common shares outstanding	30,667,371	25,262,538	30,438,669	25,262,538

See accompanying notes to the financial statements

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

	Nine Months Ended September 30, 2012	2011
Cash flows from operating activities:		
Net loss	$(16,594,090)	$(15,862,380)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	583,058	415,592
Noncash compensation	1,106,296	2,911,260
Write off of unamortized financing costs	62,391	—
Changes in operating assets and liabilities:		
Increase in accounts receivable	(100,578)	—
Increase in inventory	(566,287)	—
Decrease (increase) in prepaid expenses and other current assets	351,782	(336,036)
Increase (decrease) in accounts payable and accrued expenses	773,946	(366,642)
Increase in deferred rent	4,167	25,434
Increase in other assets	(7,501)	(248,793)
Increase in deferred revenue	150,876	—
Increase (decrease) in other current liabilities	50,904	(1,288)
Net cash used in operating activities	(14,185,036)	(13,462,853)
Cash flows from investing activities:		
Purchases of property and equipment	(3,668,410)	(58,680)
Net cash used in investing activities	(3,668,410)	(58,680)
Cash flows from financing activities:		
Proceeds from exercise of stock options	38,585	—
Proceeds from Public Offering	3,397,837	—
Expenses related to Public Offering	(303,998)	—
Net cash provided by financing activities	3,132,424	—
Net decrease in cash and cash equivalents	(14,721,022)	(13,521,533)
Cash and cash equivalents at beginning of period	27,996,871	30,520,812
Cash and cash equivalents at end of period	$ 13,275,849	$ 16,999,279
Supplemental disclosure of cash flow information:		
Non-cash investing activity:		
Re-classification of MelaFind® components from other assets to property and equipment	$ 522,014	$ —

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 commercialization of our flagship product, MelaFind®, and the further design and development of MelaFind® and our technology. MelaFind® is a non-invasive, point-of-care (in the doctor's office) instrument to aid in the detection of melanoma. MelaFind® features a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated 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 Company received the Food and Drug Administration's ("FDA") approval of the Pre-Market Approval ("PMA") application for Melafind® in November 2011 and in September 2011 the Company received Conformite Europeenne ("CE") Mark approval for MelaFind®. The Company initiated a controlled launch of MelaFind® in selected U.S. and German markets in March 2012. In March 2012, the Company began generating revenues from MelaFind®.

During the third quarter of 2012, the Company continued the MelaFind® controlled launch with additional installations of MelaFind® systems in both the U.S. and Germany. In the U.S., MelaFind® systems were placed principally in the Northeast with additional installations in certain Southern, Mid-Western and Western states.

The Company anticipates that it will continue to incur net losses for the foreseeable future in the commercialization of the Melafind® device, the conduct of a Post Approval Study ("PAS") evaluating the sensitivity of physicians in diagnosing melanomas and high-grade lesions and the false positive rate after using MelaFind®, the further development of Melafind® and the Company's technology and the expansion of its corporate infrastructure. From inception, the Company has financed operations initially through the sale of convertible preferred stock prior to becoming a public company in 2005 and subsequently through the sale of common stock.

On June 15, 2012, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") to sell shares of its common stock with aggregate gross proceeds of up to $20 million, from time to time, through an "at-the-market" equity offering program ("ATM Program") under which Cowen will act as sales agent. As of September 30, 2012, there were 989,193 shares of the Company's common stock sold through the ATM Program for gross proceeds of approximately $3.4 million and net proceeds of approximately $3.3 million. At September 30, 2012, approximately $16.6 million remains available under the Company's ATM Program.

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, 2012, the Company's total of cash and cash equivalents was approximately $13.3 million. Management believes that this cash balance along with anticipated revenues and the utilization of the Company's ATM Program will be sufficient to fund the Company's anticipated level of operations for at least the next twelve months. However, the Company will need substantial funds to broaden the commercialization of MelaFind®, including further development of a direct sales force and expansion of the Company's contract manufacturing capacity.

The net proceeds received to date and anticipated to be received from the ATM Program are intended to be used to continue the commercial launch of MelaFind® in the U.S. and the European Union, for continued research & development activities and for general corporate purposes, including working capital. There can be no assurances that the Company will be able to obtain 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, 2011.

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. REVENUE RECOGNITION

The Company considers revenue to be earned when all of the following criteria are met: persuasive evidence a sales arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. The Company's agreements with dermatologists regarding the MelaFind® system combine the elements noted above with a future service obligation. While the Company is required to place the MelaFind® systems with dermatologists for their exclusive use, ownership of the MelaFind® systems remains with the Company.

In the U.S., the Company generates revenue primarily from the sale of single-use electronic patient record cards. These cards activate the MelaFind® system, capture data and store the data for each patient visit. Additionally, the Company typically charges an initial installation fee for each MelaFind® system which covers training, delivery, supplies, maintenance and the right to use MelaFind®. In accordance with the accounting guidance regarding multiple-element arrangements, the Company defers revenue for the undelivered service element based upon the relative standalone selling prices, and recognizes the associated revenue over the related service period, generally expected to be two years.

Costs of revenue are associated with; the placement of the MelaFind® system in the doctor's office, the cost of consumables delivered at installation, the cost of the electronic record cards, technical support costs and depreciation costs of the MelaFind® system placed with the customer which remains the property of the Company. Certain product quality and manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind® are allocated to costs of goods sold and product inventory.

In Germany, the typical contract with dermatologists calls for an installation or fixed monthly fee and a per patient usage charge. Revenue generated from German contracts is recognized when earned.

3. INVENTORIES

Inventories are stated at the lower of cost (first-in, first-out) or market value. Inventory costs only include material purchases and certain overhead costs. The Company does not manufacture its products.

4. 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, use of estimates to determine the elements of our revenue and deferred revenue, and accrued expenses. Actual results could differ from these estimates.

5. RECENT ACCOUNTING PRONOUNCEMENTS

In June, 2011, the FASB issued Accounting Standard Update No 2011-05 "Presentation of Comprehensive Income" (ASU 2011-05). Under ASU 2011-05, an entity has the option to present the total of comprehensive income either in a single continuous statement of comprehensive income or in two separate but continuous statements of income and comprehensive income. The option of presentation of the components of other comprehensive income as part of the statement of change in the stockholders' equity has been eliminated. This update was applied retrospectively and was effective for the Company for the fiscal year beginning January 1, 2012. For the periods ended September 30, 2011 and September 30, 2012, comprehensive loss was equal to net loss as the Company had no other comprehensive income or loss to report in either period.

6. 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,	
	2012	2011
Common stock options	2,259,506	2,126,804
Warrants	200,000	546,781
Total	2,459,506	2,673,585

7. 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 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 third quarter of 2012 and 2011 for stock options amounted to $332 (of which $203 relates to performance milestones) and $2,177 (of which $2,031 relates to performance milestones), respectively. For the nine months ended September 2012 and 2011, compensation expense for stock options amounted to $1,106 (of which $548 relates to performance milestones) and $2,911 (of which $2,059 relates to performance milestones), respectively. Cash received from options and warrants exercised under all share-based payment arrangements for the three month periods ended September 30, 2012 and 2011 was $5 and $0, respectively, and for the nine month periods ended September 30, 2012 and 2011 cash received was $39 and $0, respectively.

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

	For the Nine Months Ended September 30, 2012	For the Nine Months Ended September 30, 2011
Expected life	6.5 years	6.5 years
Expected volatility	73.55-79.68%	70.54-76.32%%
Risk-free interest rate	.91-1.60%	1.38-3.34%
Dividend yield	0%	0%

The expected life of the options is based on the expected time to full-vesting, forfeiture and exercise. The expected volatility assumptions were 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, 2012, stock options to purchase 2,259,506 shares of common stock at exercise prices ranging from $1.00 to $11.11 per share are outstanding and exercisable at various dates through 2022.

For the three months and nine months ended September 30, 2012, the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was $2.29 and $2.56, respectively. For the three month and nine month periods ended September 30, 2011, the weighted average fair value of options granted was $1.61 and $2.14, respectively. For the three and nine month periods ended September 30, 2012 the total intrinsic value of options exercised was $3 and $77, respectively. For the three month and nine month periods ended September 30, 2011 no options were exercised.

The status of the Company's stock option plans at September 30, 2012 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, 2011	2,057,104	$ 4.35	6.6	
Granted	492,763	3.38	9.6	
Exercised	(55,623)	3.12	—	
Forfeited or expired	(234,738)	5.26	—	
Outstanding at September 30, 2012	2,259,506	$ 4.16	6.9	$ 158
Vested and exercisable at September 30, 2012	1,559,618	$ 4.02	6.1	$ 137

	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
$.01-$1.00	43,329	0.3 years	$ 1.00	43,329	$ 1.00
$1.01-$4.50	1,780,702	7.3 years	$ 3.60	1,340,089	$ 3.64
$4.51-$11.11	435,475	5.9 years	$ 6.76	176,200	$ 7.67
$.01-$11.11	2,259,506	6.9 years	$ 4.16	1,559,618	$ 4.02

As of September 30, 2012, of the total 2,259,506 options outstanding 699,888 have not vested. Of this total unvested amount, 231,450 options will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. The weighted average vesting period for the non-milestone, non-vested awards not yet recognized is 2 years.

As of September 30, 2012, of the $931 of total unrecognized compensation cost related to unvested options to be recognized, $346 is to be recognized over a period to be determined by performance-based milestones, and $585 is to be recognized over the requisite service period through 2016.

As of September 30, 2012, there were 1,395,939 shares available for future grants under the Company's 2005 Plan.

8. COMMITMENTS, CONTINGENCIES and LITIGATION

The Company is obligated under a non-cancelable operating lease for office and laboratory 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 are as follows:

Year ended December 31,	
2012 Remaining three months	$ 108
2013	461
2014	478
2015	478
2016	478
	$2,003

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® manufacturing and development team. ASKION produced the MelaFind® hand-held devices used in our pivotal clinical trials. In January of 2012, the Company entered into an expanded manufacturing agreement with ASKION to continue developmental engineering, production and testing of our hand-held devices, and to assemble and test the integrated finished MelaFind® systems to be placed within the European Union.

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 that had been used in the Company's clinical trials and the commercial units currently being manufactured. This work is expected to continue on commercial MelaFind® units beyond 2012.

In addition, we are utilizing Nexcore Technology Inc., an FDA GMP compliant and ISO 9001 certified and ISO 13485 original equipment manufacturer of medical devices in New Jersey, to provide the assembled carts and integrated MelaFind® systems for installation in the U.S.

The Company has an employment agreement with its Chairman, President and Chief Executive Officer, Dr. Joseph 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 2012.

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 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, plaintiffs filed a motion for leave to amend the consolidated amended complaint on November 18, 2011, which defendants opposed. On September 19, 2012, the court denied plaintiffs' motion for leave to amend the consolidated amended complaint. On September 28, 2012, the court reinstated and granted defendants' motion to dismiss the consolidated amended complaint. On October 22, 2012, plaintiffs filed a notice of appeal from the Judgments denying Lead Plaintiffs' motion to amend the consolidated amended complaint and granting Defendants' motion to dismiss the consolidated amended complaint.

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 any degree of 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.

9. STOCKHOLDERS' EQUITY

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 25, 2012. 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.

The CEFF terminated in May 2012 with 1,095,315 shares of common stock remaining unsold. Legal, accounting, and other costs associated with this agreement approximating $62 were charged to operations in the quarter ended June 30, 2012 as the CEFF expired. The 200,000 warrants held by Kingsbridge remain outstanding and, if not exercised, will expire in May 2014.

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.

On December 15, 2011, the Company entered into an underwriting agreement, relating to the public offering of 5,000,000 shares of the Company's common stock, at a price to the public of $3.25 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 December 16, 2011, in connection with a takedown from the Company's effective shelf registration statement. The gross proceeds to the Company from the sale of the common stock totaled approximately $16.3 million. After deducting the underwriters' discounts and commissions and other offering expenses payable by the Company, net proceeds were approximately $15 million. This offering closed on December 21, 2011. Approximately $42.2 million remained available under the Company's 2010 shelf registration at December 31, 2011.

On June 15, 2012 the Company entered into a sales agreement with Cowen and Company, LLC to sell shares of its common stock with aggregate gross proceeds of up to $20 million, from time to time, through an ATM Program. The common stock was offered and will be sold pursuant to the Company's Prospectus dated June 1, 2010 and the Company's Prospectus Supplement filed with the SEC on June 15, 2012, in connection with a takedown from the Company's effective shelf registration statement, leaving $22.2 million available under the shelf registration, assuming full utilization of the ATM Program. As of September 30, 2012, 989,193 shares of the Company's common stock were sold through the ATM Program for gross proceeds of approximately $3.4 million and net proceeds of approximately $3.3 million. At September 30, 2012, approximately $16.6 million remains available under the Company's ATM Program. During October 2012, there were 280,228 shares of Company common stock sold through the ATM for gross proceeds of approximately $0.9 million and net proceeds of approximately $0.9 million.

As of September 30, 2012, the Company had 45,000,000 shares of $0.001 par value common stock authorized and 31,323,910 shares issued and outstanding; and had 10,000,000 shares of $0.10 par value preferred stock authorized with no preferred shares issued and outstanding.

10. WARRANTS

	Issued 2007	Issued 2009	Total
Outstanding at December 31, 2011	346,781	200,000	546,781
Expired at August 3, 2012	(346,781)	—	(346,781)
Outstanding at September 30, 2012	—	200,000	200,000

In connection with the Company's private placement in August 2007, the Company issued 5-year warrants to purchase up to 500,041 shares of the Company's common stock. At August 3, 2012, 60 months from their effective date, all 346,781 of the outstanding 2007 warrants expired.

In addition, in connection with the May 7, 2009 CEFF with Kingsbridge Capital, the Company issued a 5-year warrant to Kingsbridge to purchase up to 200,000 shares of the Company's common stock at an exercise price of $11.35 per share. These 200,000 warrants are outstanding at September 30, 2012 and, if not exercised, will expire in May of 2014.

No warrants were exercised during the three and nine month periods ended September 30, 2012 and September 30, 2011, respectively.

11. 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, a former member and the former Chairman of the Company's Board of Directors, for consulting services related to the FDA approval of MelaFind® PMA application and the Company's business and financial strategy. Under this agreement, Mr. Castleman received compensation

for each month of services rendered. The Company made payments pursuant to this consulting agreement of $6 and $18 in the three and nine month periods ended September 30, 2011. The Company made no payments in the three and nine month periods ended September 30, 2012 as this consulting agreement was terminated in December 2011 at the time of Mr. Castleman's resignation from the Company's Board of Directors.

Consulting Agreement with Gerald Wagner, Ph.D

In January 2007, Dr. Wagner, Ph.D., a former member of the Company's Board of Directors, entered into an amended and restated consulting contract with the Company for consulting services related to the Company's operations. 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 may terminate 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 paid consulting costs pursuant to this agreement of $7.5 and $22.5 for the three and nine month periods ended September 30, 2012, respectively. The Company paid consulting costs pursuant to this agreement of $7.5 and $22.5 for the three and nine month periods ended September 30, 2011, respectively. Dr. Wagner resigned from the Company's Board of Directors in December 2011, with his consulting contract remaining in effect.

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, has subsequently been extended to run through September 2013, 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. The Company did not pay any amount to Ms. Egger for consulting in the three and nine month periods ended September 30, 2012. The Company paid consulting costs pursuant to this agreement of $2 and $8 for the three and nine month periods ended September 30, 2011, respectively. Ms. Egger was appointed to the Company's Board of Directors in June 2009.

12. 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®. Beginning in July 2008, KaVo is required to pay to the Company a royalty stream based upon the worldwide aggregate net sales of the licensed product, as defined in the license agreement, or a set minimum. During the three and nine months ended September 30, 2012 and September 30, 2011, respectively, the Company earned $5 and $15 as the pro-rated portion of the minimum royalty as KaVo has not re-launched the product as of September 30, 2012.

13. SUBSEQUENT EVENTS

On October 8, 2012 the Company signed a lease for shared office space in Munich Germany to support its German operations. This lease calls for monthly lease payments of approximately $4,000 per month. The lease is subject to escalations for increases in operating expenses however the lease is cancellable with four months notice.

On October 12, 2012 and October 15, 2012, in connection with its supply of MelaFind® units, the Company issued a purchase order for approximately $2.8 million pursuant to its Production Agreement dated January 6, 2012 with Askion GmbH and a purchase order for approximately $1.1 million pursuant to its Production Agreement dated January 6, 2012 with Nexcore Technology, Inc., respectively.

During October 2012, 280,228 shares of Company common stock, for gross proceeds of approximately $0.9 million, were sold through the Company's ATM Program. Approximately $15.7 million remains available under the ATM Program as of October 31, 2012. The Company had 31,604,138 shares of common stock issued and outstanding as of October 31, 2012.

ITEM 2.

MELA SCIENCES, INC.
MANAGEMENT'S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
(In thousands, except for share and per share data)

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, 2011 ("Form 10-K").

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

Overview

We are a medical device company focused on the commercialization of our flagship product, MelaFind®, and the further design and development of MelaFind® and our technology. MelaFind® is a non-invasive, point-of-care (in the doctor's office) instrument to aid in the detection of melanoma. MelaFind® features a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The data are then analyzed utilizing sophisticated 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.

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, 2012, we had an accumulated deficit of approximately $136.1 million. We expect to continue to spend significant amounts on the commercialization and further development of MelaFind® and the development of our technology.

The Company received the Food and Drug Administration's ("FDA") approval of the Pre-Market Approval ("PMA") application for Melafind® in November 2011 and in September 2011 the Company received Conformite Europeenne ("CE") Mark approval for MelaFind®. The Company initiated a controlled launch of MelaFind® in selected U.S. and German markets in March 2012. In March 2012, the Company began generating revenues from MelaFind®.

During the third quarter of 2012, the Company continued the MelaFind® controlled launch with additional installations of MelaFind® systems in both the U.S. and Germany. Additions were made to the direct sales force and field technical support capabilities of the Company commensurate with these additional installations and an increasing demand for MelaFind®. Also during the quarter, the production levels of our contract manufacturers were increased to address the increasing demand for MelaFind® systems. In the U.S., MelaFind® systems were placed principally in the Northeast with additional installations in certain Southern, Mid-Western and Western states.

The Company anticipates that it will continue to incur net losses for the foreseeable future in the commercialization of the Melafind® device, the conduct of a Post Approval Study ("PAS") evaluating the sensitivity of physicians in diagnosing melanomas and high-grade lesions and the false positive rate after using MelaFind®, the further development of Melafind® and the Company's technology and the expansion of its corporate infrastructure.

Liquidity and Capital Resources

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 25, 2012. 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.

The Company did not sell any stock to Kingsbridge Capital Limited under the CEFF in the three or nine months ended September 30, 2012 and September 30, 2011, respectively. The CEFF terminated in May 2012 with 1,095,315 shares of common stock remaining unsold. Legal, accounting, and other costs associated with this agreement approximating $62 have been charged to operations in the quarter ended June 30, 2012 as the CEFF expired. The 200,000 warrants held by Kingsbridge remain outstanding and, if not exercised, will expire in May 2014.

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.

On December 15, 2011, the Company entered into an underwriting agreement, relating to the public offering of 5,000,000 shares of the Company's common stock, at a price to the public of $3.25 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 December 16, 2011, in connection with a takedown from the Company's effective shelf registration statement. The gross proceeds to the Company from the sale of the common stock totaled approximately $16.3 million. After deducting the underwriters' discounts and commissions and other offering expenses payable by the Company, net proceeds were approximately $15 million. This offering closed on December 21, 2011. Approximately $42.2 million remained available under the Company's 2010 shelf registration at December 31, 2011.

On June 15, 2012 the Company entered into a sales agreement with Cowen and Company, LLC to sell shares of its common stock with aggregate gross proceeds of up to $20 million, from time to time, through an ATM Program. The common stock was offered and will be sold pursuant to the Company's Prospectus dated June 1, 2010 and the Company's Prospectus Supplement filed with the SEC on June 15, 2012, in connection with a takedown from the Company's effective shelf registration statement, leaving $22.2 million available under the shelf registration, assuming full utilization of the ATM Program. As of September 30, 2012, 989,193 shares of the Company's common stock were sold through the ATM Program for gross proceeds of approximately $3.4 million and net proceeds of approximately $3.3 million. At September 30, 2012, approximately $16.6 million remains available under the Company's ATM Program. During October 2012 there were 280,228 shares of Company common stock sold through the ATM for gross proceeds of approximately $0.9 million and net proceeds of approximately $0.9 million.

Most of our expenditures prior to commercialization in March 2012 had been for research and development activities and general and administrative expenses. Research and development expenses represented costs incurred for product development, clinical trials, activities related to regulatory filings, and manufacturing development efforts. Subsequent to the commercial launch of MelaFind®, certain costs previously classified as research and development expenses are now classified as cost of sales or general and administrative expenses.

We expense all of our research and development costs as they are incurred.

From time to time we plan to issue significant purchase orders, to be paid and delivered over time, under master production agreements and similar arrangements with our contract manufacturers in order to satisfy the projected placements of MelaFind® systems. Certain purchase orders may be for very substantial amounts and represent firm commitments to purchase MelaFind® systems (or components thereof). The timing and size of these purchase orders will depend on our market forecasts and our available capital resources.

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, 2012, the Company's total of cash and cash equivalents was approximately $13.3 million. The Company will require additional funds to achieve significant commercialization of MelaFind®. However, there can be no assurances that the Company will be able to obtain 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, 2012 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 $14,185 for the nine months ended September 30, 2012. For the corresponding period in 2011, net cash used in operations was $13,463. In both periods, cash used in operations was attributable to net losses after an adjustment for non-cash charges related to depreciation/amortization, share-based compensation, deferred rent, deferred revenue, the acquisition of MelaFind® related inventory and other changes in operating assets and liabilities.

Cash Flows from Investing Activities

For the nine months ended September 30, 2012, there was $3,668 net cash used in our investing activities, principally for the purchase of MelaFind® systems and components. For the corresponding period in 2011, $59 net cash was used in our investing activities, principally for the purchase of fixed assets.

Cash Flows from Financing Activities

For the nine months ended September 30, 2012, there was $3,132 provided by our financing activities principally from the net proceeds from the Company's ATM Program and proceeds from the exercise of stock options less additional costs from our December 2011 public offering. For the nine months ended September 30, 2011, no net cash was provided by or used in our financing activities.

Operating Capital and Capital Expenditure Requirements

We face certain risks and uncertainties, which are present in many emerging medical device companies. At September 30, 2012, we had an accumulated deficit of approximately $136.1 million. We anticipate that we will continue to incur net losses for the foreseeable future as we proceed with the MelaFind® commercialization process, the conduct of a Post Approval Study ("PAS") evaluating the sensitivity of physicians in diagnosing melanomas and high-grade lesions and the false positive rate after using MelaFind®, the further development of Melafind® and the Company's technology and the expansion of its corporate infrastructure. However, we will need substantial funds to broaden the commercialization of Melafind®. The timing and amount of any additional funding the Company may require to broaden the commercialization of Melafind® will be affected by the commercial success of the product. The funding could be in the form of either additional equity or debt financing. We believe that our current cash and cash equivalents, anticipated revenue and the utilization of the Company's ATM Program will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next twelve months. However, if our existing cash is insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain a credit facility, which will be even more difficult than a traditional financing due to the lack of available capital as a result of the recent global economic crisis. If additional funds are raised through the issuance of debt securities, these securities would have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of, delay or eliminate some or all of planned product research development and commercialization activities, which could harm our business.

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

- the cost of commercialization activities, including product marketing and building a domestic direct sales force and conducting activities in Germany and ultimately throughout the European Union ("EU");
- the costs of maintaining regulatory approval;

- the amount of direct payments we are able to obtain from physicians utilizing MelaFind®;
- reimbursement amounts for the use of MelaFind® that physicians are able to obtain from Medicare and third party payers;
- the success of our research and development efforts in product creation and enhancement, and meeting competitive services and technologies;
- the schedule, costs, and results of our clinical trials;
- the costs of maintaining or potentially building our MelaFind® supply and other manufacturing expenses;
- our ability to establish and maintain any collaborative, licensing or other arrangements, and the terms and timing of any such arrangements;
- the costs involved in defending any patent infringement actions or other litigation claims brought against us by third parties; and
- the costs of filing, prosecuting, defending and enforcing any patent claims or other rights.

Contractual Obligations (in thousands)

The following table summarizes our outstanding contractual obligations as of September 30, 2012, 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
Operating leases	$2,003	$ 454	$ 952	$ 597

Our long-term obligations represent a non-cancelable operating lease for our laboratory, assembly, and office space which expires in December of 2016. The lease is for approximately 21,700 square feet of space.

Results of Operations (in thousands)

In the nine months ended September 30, 2012, the Company has evolved from being exclusively an R&D company prior to the MelaFind® launch to a commercial company with the controlled installation of MelaFind® systems in the U.S. and Germany. Additions have been made to the direct sales force and field technical support capabilities of the Company commensurate with these additional installations and increasing demand for MelaFind®. The production levels of our contract manufacturers have been increased to address the increasing demand for MelaFind® systems. For the first two months of 2012 the Company continued to record all transactions as an R&D company, as it had in 2011. Subsequent to the commercial launch of MelaFind®, certain costs previously classified as research and development expenses are now classified as cost of sales, inventory or general administrative expenses. Sales and marketing efforts have been increased in the first nine months of 2012 prior and subsequent to the commercial launch of MelaFind®.

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

Sales

Invoicing in the three months ended September 30, 2012 totaled $132, with revenue of $69 and deferred revenue of $63 recorded as the Company continued its controlled commercial launch of the MelaFind® product which commenced during March 2012. Prior to the commercial launch of MelaFind®, the Company had not recorded any product revenue or deferred revenue since the discontinuance of our Difoti product in 2005. In general, the Company signs a user agreement with its customers that includes an installation fee for the placement of the MelaFind® system and provides for the sale of its electronic patient record cards and consumables which are needed to operate the system. The Company is addressing unique aspects of the European marketplace through variations of the user agreement. Deferred revenue reflects the timed recognition of the installation fee revenue over the term of the user agreement, which is generally two years.

Cost of Sales

Costs of $569 were recorded as associated with the realization of MelaFind® revenue and deferred revenue during the three months ended September 30, 2012. These costs were made up of direct costs associated with the placement of the MelaFind® system in the doctor’s office, the cost of consumables delivered at installation, the cost of the electronic record cards, technical support costs and depreciation costs of the MelaFind® system placed with the customer which remains the property of the Company. Certain product quality and manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind® are allocated to costs of goods sold and product inventory. The Company had not recorded any product cost of sales prior to the commercial launch of MelaFind®.

Research and Development Expense

Research and development ("R&D") expenses experienced an overall decrease of $1,039 or 43% in the three months ended September 30, 2012 below the comparable period a year earlier. This decrease was principally due to the re-classification to general and administrative ("G&A") expense of regulatory expenses and clinical expenses, and the re-classification of quality expenses, technical support expenses, and certain operating expenses to cost of sales or inventory. Exclusive of the reclassified costs, R&D expenses increased $155 or 12% over the comparable period of 2011. The increase in software development costs of $174 and of US development expense of $106 was offset by a decrease in R&D expense at Askion in Germany of $125.

General and Administrative Expense

General and administrative ("G&A") expenses experienced an overall decrease of $221 or 6% for the three months ended September 30, 2012 below the comparable period a year earlier. With the reclassification of certain clinical and regulatory costs from R&D, the G&A expenses showed a year-to-year decrease of approximately $1,311. For the three months ended September 30, 2012, G&A share-based compensation is $1,689 below the comparable period a year earlier. Approval of the MelaFind® PMA in 2011 resulted in the vesting of a significant number of performance-based options and the related charges to share-based compensation. Marketing expenses increased $625 from a year earlier. Regulatory costs decreased $287 from the level of the comparable period a year earlier.

Interest Income

Interest income for the three months ended September 30, 2012 decreased to $6 from $11 in the comparable period of 2011. Interest income decreased primarily as a result of smaller cash balances earning interest during the period in 2012.

Other Income

Other income for the three months ended September 30, 2012 and 2011, includes the $5 royalty minimum we earn each quarter from Kavo on the sale/licensing of our discontinued DEFOTI product.

Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

Sales

Invoicing in the nine months ended September 30, 2012 totaled $307, with revenue of $156 and deferred revenue of $151 recorded as the Company continued its controlled commercial launch of the MelaFind® product which commenced during March 2012. Prior to the commercial launch of MelaFind®, the Company had not recorded any product revenue or deferred revenue since the discontinuance of our Difoti product in 2005. In general, the Company signs a user agreement with its customers that includes an installation fee for the placement of the MelaFind® system and provides for the sale of its electronic patient record cards and consumables which are needed to operate the system. The Company is addressing unique aspects of the European marketplace through variations of the user agreement. Deferred revenue reflects the timed recognition of the installation fee revenue over the term of the user agreement, which is generally two years.

Cost of Sales

Costs of $1,071 were recorded as associated with the realization of MelaFind® revenue and deferred revenue during the nine months ended September 30, 2012. These costs were made up of direct costs associated with the placement of the MelaFind® system in the doctor's office, the cost of consumables delivered at installation, the cost of the electronic record cards, technical support costs and depreciation costs of the MelaFind® system placed with the customer which remains the property of the Company. Certain product quality and manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind® are allocated to costs of goods sold and product inventory. The Company had not recorded any product cost of sales prior to the commercial launch of MelaFind®.

Research and Development Expense

Research and development ("R&D") expenses experienced an overall decrease of $2,128 or 28% in the nine months ended September 30, 2012 below the comparable period a year earlier. This decrease was principally due to the re-classification to general and administrative ("G&A") expense of certain regulatory expenses and clinical expenses, and the re-classification of certain quality expenses, technical support expenses, and certain operating expenses to cost of sales or inventory. Exclusive of the reclassified costs, R&D expenses increased $231 over the comparable period of 2011. Software development costs increased $484 and US Development expenses increased $506 while Askion Development costs decreased $844 in the nine month period of 2012 compared to 2011.

General and Administrative Expense

General and administrative ("G&A") expenses experienced an overall increase of $1,924 or 23% for the nine months ended September 30, 2012 above the comparable period a year earlier. With the reclassification of certain clinical and regulatory costs from R&D, the G&A expenses showed a year-to-year decrease of approximately $151. For the nine months ended September 30, 2012, share-based compensation is $1,713 below the comparable period a year earlier. Approval of the MelaFind PMA in 2011 resulted in the vesting of a significant number of performance-based options and the related charges to share-based compensation. Marketing expenses increased $1,423 and Information Technology costs increased $352 while Regulatory costs decreased $234 from the level of the comparable period a year earlier.

Interest Income

Interest income for the nine months ended September 30, 2012 decreased to $28 from $45 in the comparable period of 2011. Interest income decreased primarily as a result of smaller cash balances during the period in 2012.

Other Income

Other income for the nine months ended September 30, 2012 and 2011, is primarily the $5 royalty minimum we earn each quarter from Kavo on the sale/licensing of our discontinued DEFOTI product.

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 stock-based compensation charges, use of estimates to determine the elements of our revenue and deferred revenue, and accrued expenses are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

The Company considers revenue to be earned when all of the following criteria are met: persuasive evidence a sales arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. The Company's agreements with dermatologists regarding the MelaFind® system combines the elements noted above with a future service obligation. While the Company is required to place the MelaFind® system with dermatologists for their exclusive use, ownership of the MelaFind® system remains with the Company.

In the U.S., the Company generates revenue primarily from the sale of single-use electronic patient record cards. These cards activate the MelaFind® system, capture data and store the data for each patient visit. Additionally, the Company typically charges an initial installation fee for each MelaFind® system which covers training, delivery, supplies, maintenance and the right to use MelaFind®. In accordance with the accounting guidance regarding multiple-element arrangements, the Company defers revenue for the undelivered service element based upon the relative standalone selling prices, and recognizes the associated revenue over the related service period, generally expected to be two years.

Costs of revenue are associated with; the placement of the MelaFind® system in the doctor's office, the cost of consumables delivered at installation, the cost of the electronic record cards, technical support costs and depreciation costs of the MelaFind® system placed with the customer which remains the property of the Company. Certain product quality and manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind® are allocated to costs of goods sold and product inventory.

In Germany, the typical contract with dermatologists calls for an installation or fixed monthly fee and a per patient usage charge. Revenue generated from German contracts is recognized when earned.

Stock-Based Compensation

We account 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 in accordance with FASB ASC 505-50, “Equity Based Payments to Non-Employees.”

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

Accrued Expenses

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

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

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

In June, 2011, the FASB issued Accounting Standard Update No 2011-05 “Presentation of Comprehensive Income” (ASU 2011-05). Under ASU 2011-05, an entity has the option to present the total of comprehensive income either in a single continuous statement of comprehensive income or in two separate but continuous statements of income and comprehensive income. The option of presentation of the components of other comprehensive income as part of the statement of change in the stockholders’ equity has been eliminated. This update was applied retrospectively and was effective for the Company for the fiscal year beginning January 1, 2012. For the year ended December 31, 2011 and as of September 30, 2012, comprehensive loss was equal to net loss as the Company had no other comprehensive income or loss to report in either period.

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. In accordance with the Company’s investment policy, 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, 2012, 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, 2012 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 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, plaintiffs filed a motion for leave to amend the consolidated amended complaint on November 18, 2011, which defendants opposed. On September 19, 2012, the court denied plaintiffs' motion for leave to amend the consolidated amended complaint. On September 28, 2012, the court reinstated and granted defendants' motion to dismiss the consolidated amended complaint. On October 22, 2012, plaintiffs filed a notice of appeal from the Judgments denying Lead Plaintiffs' motion to amend the consolidated amended complaint and granting Defendants' motion to dismiss the consolidated amended complaint.

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 any degree of 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, 2011. In addition, the following risk factors have materially changed during the three months ended September 30, 2012:

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

Since 1999, we have primarily financed our operations 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, 2012 was approximately $16.6 million, and as of September 30, 2012, we had an accumulated deficit of approximately $136.1 million. Our research and development expenses may increase in connection with our continued commercialization and development activities related to MelaFind®. Having commenced commercialization in March 2012, we expect to incur significant sales, marketing, contract manufacturing and inventory build-up 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 continue commercialization and continue development of MelaFind® enhancements or other products without additional funding and we will not be able to achieve significant commercialization without additional funding.

As of September 30, 2012 we had approximately $13.3 million in cash and cash equivalents. Our operations have consumed substantial amounts of cash for each of the last ten years and we expect that our cash used by operations will increase significantly in each of the next several years. We currently believe that our available cash and cash equivalents, utilization of our ATM and anticipated revenue will be sufficient to fund our anticipated levels of operations for at least the next twelve months. However, we will need substantial funds to broaden the commercial ization of MelaFind®, including further development of a direct sales force and expansion of our contract manufacturing capacity. We also expect to continue to spend funds on research and development and product enhancements. Our business or operations may change in a manner that would consume available resources more rapidly than we anticipate. The amount of funding we will need will depend on many factors, including:

- the cost of commercialization activities, including product marketing and building a domestic direct sales force and conducting activities in Germany and ultimately throughout the European Union ("EU");
- the costs of maintaining regulatory approval;
- the amount of direct payments we are able to obtain from physicians utilizing MelaFind®;
- reimbursement amounts for the use of MelaFind® that physicians are able to obtain from Medicare and third party payers;
- the success of our research and development efforts in product creation and enhancement, and meeting competitive services and technologies;
- the schedule, costs and results of any clinical trials and studies;
- the costs of maintaining or potentially building our MelaFind® supply and other manufacturing expenses;
- our ability to establish and maintain any collaborative, licensing or other arrangements, and the terms and timing of any such arrangements;
- the costs involved in defending any patent infringement actions or other litigation claims brought against us by third parties; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other rights.

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 also may have to reduce marketing, customer support and other resources devoted to our products. 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, or that may require us to grant a security interest in our assets. 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.

Significant purchases of MelaFind® systems from our contract manufacturers will result in greater amounts of property and equipment on our balance sheet which will lead, to among other things, increased depreciation expenses on our income statement and may affect our return on capital investment.

From time to time we plan to issue significant purchase orders, to be paid and delivered over time, under master production agreements and similar arrangements with our contract manufacturers in order to satisfy the projected placements of MelaFind® systems. Certain purchase orders may be for very substantial amounts, some of which may be in excess of $1 million, and represent firm commitments to purchase MelaFind® systems (or components thereof). The timing and size of these purchase orders will depend on our market forecasts and our available capital resources. As we purchase larger numbers of MelaFind® systems, the amount of property and equipment on our balance sheet will correspondingly increase. The increased amount of property and equipment on our balance sheet will result in larger amounts of depreciation expense which will impact the amount of net income (loss) reported on our income statement. If we are unable to place purchased MelaFind® systems we may experience expenses for obsolescence. The destruction or loss of any of the placed MelaFind® systems may also result in loss above and beyond the amounts for which they are insured.

Our current business model entails an immediate upfront expense to the Company in connection with the purchase of a MelaFind® system, the cost of which is then offset by an initial installation fee and a future revenue stream to the Company every time the system is used. It may take several years before the anticipated income from a placed MelaFind® system is sufficient to recover the unit's original cost.

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

None

Item 3. Defaults Upon Senior Securities

Not applicable

Item 4. Mine Safety Disclosures

Not applicable

Item 5. Other Information

(a) Not applicable

(b) Not applicable

Table of Contents

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

Table of Contents

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
Senior Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Date: November 7, 2012

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

Exhibit 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

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 7, 2012

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

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

Exhibit 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

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 7, 2012

/s/ Richard I. Steinhart

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

Exhibit 32.1

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, 2012 (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
Chairman, President and Chief Executive Officer
(Principal Executive Officer)
November 7, 2012

/s/ Richard I. Steinhart
Richard I. Steinhart
Senior Vice President & Chief Financial Officer
(Principal Accounting and Financial Officer)
November 7, 2012

* 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.