

MELA SCIENCES, INC. /NY (MELA)

10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filed on 05/03/2012

Filed Period 03/31/2012

THOMSON REUTERS ACCELUS™



THOMSON REUTERS

**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 March 31, 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
(State or Other Jurisdiction of
Incorporation or Organization)
50 South Buckhout Street, Suite 1
Irvington, New York
(Address of Principal Executive offices)

13-3986004
(I.R.S. Employer
Identification No.)

10533
(Zip Code)

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

(Former name if changed since last report)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

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 April 26, 2012: 30,332,217 shares of the Registrant's common stock were outstanding.

[Table of Contents](#)

MELA Sciences, Inc.
Table of Contents

	<u>Page</u>
PART I. FINANCIAL INFORMATION	
ITEM 1. Financial Statements	
Condensed Balance Sheets as of March 31, 2012 (unaudited) and December 31, 2011	2
Condensed Statements of Operations (unaudited) for the three month periods ended March 31, 2012 and 2011	3
Condensed Statements of Cash Flows (unaudited) for the three month periods ended March 31, 2012 and 2011	4
Notes to Condensed Financial Statements (unaudited)	5
ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	13
ITEM 3. Quantitative and Qualitative Disclosures about Market Risk	20
ITEM 4. Controls and Procedures	20
PART II. OTHER INFORMATION	
ITEM 1. Legal Proceedings	21
ITEM 1A. Risk Factors	22
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds	23
ITEM 3. Defaults Upon Senior Securities	23
ITEM 4. Mine Safety Disclosures	23
ITEM 5. Other Information	23
ITEM 6. Exhibits	24
SIGNATURES	25
EXHIBIT INDEX	

[Table of Contents](#)

MELA SCIENCES, INC.
CONDENSED BALANCE SHEETS

	March 31,	December 31,
	2012	2011
	(unaudited)	*
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 22,301,266	\$ 27,996,871
Accounts receivable	12,078	—
Inventory	400,363	—
Prepaid expenses and other current assets	816,206	1,061,550
Total Current Assets	23,529,913	29,058,421
Property and equipment, net	2,411,815	1,626,791
Patents and trademarks, net	56,233	59,208
Deferred financing costs	62,391	62,391
Other assets	64,484	586,498
Total Assets	\$ 26,124,836	\$ 31,393,309
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable (includes related parties of \$49,750 and \$36,027 as of March 31, 2012 and December 31, 2011, respectively)	\$ 940,117	\$ 670,950
Accrued expenses	551,978	745,754
Deferred placement revenue	17,250	—
Other current liabilities	44,880	30,993
Total Current Liabilities	1,554,225	1,447,697
Long Term Liabilities:		
Deferred rent	139,605	138,216
Total Long Term Liabilities	139,605	138,216
Total Liabilities	1,693,830	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 30,332,217 shares at March 31, 2012 and 30,307,538 at December 31, 2011	30,332	30,308
Additional paid-in capital	149,681,035	149,304,424
Accumulated deficit	(125,280,361)	(119,527,336)
Stockholders' Equity	24,431,006	29,807,396
Total Liabilities and Stockholders' Equity	\$ 26,124,836	\$ 31,393,309

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

See accompanying notes to the financial statements

[Table of Contents](#)

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

	<u>Three months ended March 31,</u>	
	<u>2012</u>	<u>2011</u>
Revenue	\$ 11,250	\$ —
Cost of revenue	130,410	—
Gross profit	(119,160)	—
Operating expenses:		
Research and development	2,434,758	2,576,128
General and administrative	3,217,491	2,393,120
Operating loss	(5,771,409)	(4,969,248)
Interest income	13,384	20,531
Other income, net	5,000	6,648
Net loss	\$ (5,753,025)	\$ (4,942,069)
Basic and diluted net loss per common share	\$ (0.19)	\$ (0.20)
Basic and diluted weighted average number of common shares outstanding	30,313,905	25,262,538

See accompanying notes to the financial statements

[Table of Contents](#)

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

	Three Months Ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (5,753,025)	\$ (4,942,069)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	148,044	147,086
Noncash compensation	347,618	170,646
Changes in operating assets and liabilities:		
Increase in accounts receivable	(12,078)	—
Increase in inventory	(310,090)	—
Decrease in prepaid expenses and other current assets	155,071	156,014
Increase (decrease) in accounts payable and accrued expenses	75,391	(19,243)
Increase in deferred rent	1,389	8,478
Increase in deferred placement revenue	17,250	—
Increase in other current liabilities	13,887	7,093
Net cash used in operating activities	(5,316,543)	(4,471,995)
Cash flows from investing activities:		
Purchases of property and equipment	(408,079)	(7,645)
Net cash used in investing activities	(408,079)	(7,645)
Cash flows from financing activities:		
Proceeds from exercise of stock options	33,310	—
Expenses related to 2011 Public Offering	(4,293)	—
Net cash provided by financing activities	29,017	—
Net decrease in cash and cash equivalents	(5,695,605)	(4,479,640)
Cash and cash equivalents at beginning of period	27,996,871	30,520,812
Cash and cash equivalents at end of period	\$ 22,301,266	\$ 26,041,172
Supplemental disclosure of cash flow information:		
Non-cash investing activity:		
Reclassification 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 components of the MelaFind[®] system include:

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

During March 2012, the Company placed the first commercial MelaFind[®] systems in the U.S. and Germany, and intends to continue with a controlled launch of MelaFind[®] in selected U.S. and European markets.

In August 2011, the Company received the International Organization for Standardization ("ISO") 13485 certification of the Company's comprehensive management system for the design and manufacture of medical devices. In September 2011, the Company received Conformite Europeenne ("CE") Mark approval for MelaFind[®]. With CE Mark approval, the Company has the ability to market MelaFind[®] to dermatologists across the European Union and in certain other countries.

The Company received written approval from the FDA for the MelaFind[®] PMA application on November 1, 2011. As a condition of PMA approval, the Company committed to conduct 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[®].

In the first quarter of 2012, the Company supported MelaFind[®] pre-launch studies conducted by selected dermatologists in the U.S. and Germany. Enhancements to MelaFind[®] were effected based on information gathered in these pre-launch studies, leading to the first commercial MelaFind[®] systems being placed in the U.S. and Germany during March 2012.

Prior to the commercial launch of MelaFind[®] in the first quarter of 2012, the Company had not generated any revenues from MelaFind[®].

[Table of Contents](#)

The Company anticipates that it will continue to incur net losses for the foreseeable future in the commercialization of the Melafind[®] device and the further development of Melafind[®] and the Company's technology. From inception, the Company has financed operations primarily through the sale of convertible preferred stock and subsequently sold common stock as part of an initial public offering in October 2005, private placements in November 2006 and August 2007, registered direct offerings which closed in August 2008 and July 2009, underwritten public offerings in July 2010 and December 2011, and the committed equity financing facility ("CEFF") with Kingsbridge Capital Limited in the second half of 2009 and first quarter of 2010.

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

As of March 31, 2012, the Company's total of cash and cash equivalents was approximately \$22.3 million. Management believes that this cash balance will be sufficient to fund the Company's anticipated level of operations for at least the next twelve months. However, the Company will need substantial funds to broaden the commercial expansion of MelaFind[®], including development of a direct sales force and expansion of the Company's contract manufacturing capacity. There can be no assurances that the Company will be able to raise additional financing in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term. In the event that the Company is unable to raise additional funds, the Company has the ability and intent to reduce certain discretionary expenditures.

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

[Table of Contents](#)

3. INVENTORIES

Inventories are stated at the lower of cost (first-in, first-out) or market value. Inventory costs include solely material purchases as the Company does not manufacture 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 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 fiscal year beginning January 1, 2012. For the year ended December 31, 2011 and as of March 31, 2012, comprehensive loss was equal to net loss as the Company had no comprehensive income 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:

	<u>March 31,</u>	
	<u>2012</u>	<u>2011</u>
Common stock options	2,079,306	2,142,879
Warrants	546,781	546,781
Total	<u>2,626,087</u>	<u>2,689,660</u>

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.

[Table of Contents](#)

The compensation expense recognized in the Statement of Operations in the first quarter of 2012 and 2011 for stock options amounted to \$348 (of which \$146 relates to performance milestones) and \$171 (of which \$15 relates to performance milestones), respectively. Cash received from options and warrants exercised under all share-based payment arrangements for the three months ended March 31, 2012 was \$33. There were not any options or warrants exercised during the three months ended March 31, 2011.

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 Three Months Ended March 31, 2012	For the Three Months Ended March 31, 2011
Expected life	6.5 years	6.5 years
Expected volatility	79.68%	76.32%
Risk-free interest rate	1.40-1.51%	2.72-2.92%
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 March 31, 2012, stock options to purchase 2,079,306 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.

During the three months ended March 31, 2012, the weighted average fair value of options granted, estimated as of the grant date using the Black-Scholes option valuation model, was \$2.62. For the three month period ended March 31, 2011, the weighted average fair value of options granted was \$2.59. For the three months ended March 31, 2012 the total intrinsic value of options exercised was \$74. During the three months ended March 31, 2011 no options were exercised.

The status of the Company's stock option plans at March 31, 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	140,000	3.72	—	
Exercised	(53,123)	3.17	—	
Forfeited or expired	(64,675)	7.06	—	
Outstanding at March 31, 2012	<u>2,079,306</u>	\$ 4.25	6.8	\$ 1,587
Vested and exercisable at March 31, 2012	<u>1,563,106</u>	\$ 4.05	6.3	\$ 1,263

	Options Outstanding			Options Exercisable	
	Number	Contractual Life	Weighted- Average Remaining Exercise Price	Number	Weighted- Average Exercise Price
Range of Exercise Prices	Outstanding	Life	Price	Exercisable	Price
\$.01-\$1.00	43,329	0.8 years	\$ 1.00	43,329	\$ 1.00
\$1.01-\$4.50	1,633,002	7.3 years	\$ 3.60	1,343,652	\$ 3.65
\$4.51-\$11.11	402,975	5.3 years	\$ 7.24	176,125	\$ 7.84
\$.01-\$11.11	<u>2,079,306</u>	6.8 years	\$ 4.25	<u>1,563,106</u>	\$ 4.05

[Table of Contents](#)

As of March 31, 2012, of the total 2,079,306 options outstanding, 516,200 have not vested. Of this total unvested amount, 166,475 options will vest upon the attainment of certain milestones, and the balance will vest over the requisite service period. The weighted average vesting period for the non-milestone, non-vested awards not yet recognized is 1.7 years.

As of March 31, 2012, of the \$910 of total unrecognized compensation cost related to unvested options to be recognized, \$517 is to be recognized over a period to be determined by performance-based milestones, and \$393 is to be recognized over the requisite service period through 2016.

As of March 31, 2012, there were 1,578,639 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, lab, and manufacturing 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 nine months	322
2013	461
2014	478
2015	478
2016	478
	<u>\$ 2,217</u>

Rental payments are recognized as rent expense on a straight-line basis over the term of the lease. In April 2012, the Company entered into an agreement, effective May 1, 2012, to amend the existing lease for laboratory, assembly and office space which runs through December 2016. This amendment increases the previously leased space by 1,700 square feet at an annual rental of \$22.

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 device, and to assemble and test the integrated finished MelaFind[®] system, including the cart, for units to be sold 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 used in the Company's pivotal clinical trials and the commercial units currently being manufactured. This work is expected to continue on commercial MelaFind[®] units beyond 2012.

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

[Table of Contents](#)

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, the parties filed a stipulation on October 19, 2011 in which plaintiff stated its intention to file a motion seeking leave to amend its complaint. Defendants withdrew the outstanding motion to dismiss the current Amended Complaint without prejudice to renew it at a later date. On November 18, 2011, plaintiffs filed their motion for leave to amend the consolidated amended complaint. On December 18, 2011, defendants filed an opposition to plaintiff's motion for leave to amend the consolidated amended complaint. On February 8, 2012, plaintiffs filed their reply to defendants' opposition to the motion. On March 16, 2012, plaintiffs filed a revised proposed second amended complaint. On March 30, 2012, defendants filed a surreply in further opposition to the motion. On April 16, 2012, plaintiffs filed a surreply in further support of the motion.

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 subject to various conditions for individual sales, including dollar, timing, and trading volume limitations, a minimum market per share price, and other contractual and regulatory requirements.

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

The Company did not sell any stock to Kingsbridge Capital Limited under the CEFF in the three months ended March 31, 2012 and March 31, 2011, respectively. As of March 31, 2012, 1,095,315 shares of common stock remain available for sale under the CEFF, exclusive of the 200,000 outstanding warrants held by Kingsbridge. Legal, accounting, and other costs associated with this agreement approximating \$62 have been deferred and will be charged to equity as a reduction of future proceeds from the CEFF or operations should management decide to abandon the CEFF which is set to expire in May of 2012.

[Table of Contents](#)

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. The gross proceeds to the Company from the sale of the common stock totaled \$16.5 million. After deducting the underwriters' discounts and commissions and other offering expenses, net proceeds were approximately \$15.2 million. This offering closed on July 6, 2010.

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 Securities and Exchange Commission (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 remains available under the Company's 2010 shelf registration statement as of March 31, 2012.

As of March 31, 2012, the Company had 45,000,000 shares of \$0.001 par value common stock authorized and 30,332,217 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
Outstanding at March 31, 2012	346,781	200,000	546,781

In connection with the Company's private placement in August 2007, the Company issued warrants to purchase up to 500,041 shares of the Company's common stock. At March 31, 2012, 346,781 of the 2007 warrants were outstanding. The 2007 outstanding warrants are exercisable at a price of \$8.00 per share and if not exercised will expire in August of 2012.

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 March 31, 2012.

No warrants were exercised during the three months ended March 31, 2012 and March 31, 2011, respectively.

[Table of Contents](#)

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, 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 in the three month period ended March 31, 2011. 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 will end at the option of Dr. Wagner or the Company at any time, by providing fifteen days' prior written notice, or immediately upon the mutual agreement of the Company and Dr. Wagner. The Company paid consulting costs pursuant to this agreement of \$7.5 in each of the three month periods ended March 31, 2012 and March 31, 2011. 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, and has subsequently been extended to run through September 2012, and may be terminated by either party with 30 days notice. Under the terms of the agreement, Ms. Egger is entitled to receive a consulting fee of \$1.6 per day. The Company did not pay Ms. Egger for consulting in the three month period ended March 31, 2012 and paid \$22 in the three month period ended March 31, 2011. Ms. Egger was appointed to the Company's Board of Directors as of June 10, 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 months ended March 31, 2012 and March 31, 2011, the Company earned \$5 as the pro-rated portion of the minimum royalty as KaVo has not re-launched the product as of March 31, 2012.

13. SUBSEQUENT EVENTS

In April 2012, the Company entered into an agreement, effective May 1, 2012, to amend the existing lease for laboratory, assembly and office space which runs through December 2016. This amendment increases the previously leased space by 1,700 square feet at an annual rental of \$22.

[Table of Contents](#)

ITEM 2.

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

This management's discussion and analysis of financial condition and results of operations is intended to provide information to help you better understand and evaluate our financial condition and results of operations. We recommend that you read this section in conjunction with our unaudited condensed financial statements and accompanying notes included under Part I, Item 1 of this Quarterly Report and our financial statements and accompanying notes in our Annual Report on Form 10-K for the year ended December 31, 2011.

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," 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 March 31, 2012, we had an accumulated deficit of approximately \$125.3 million. We expect to continue to spend significant amounts on the commercialization and further development of MelaFind[®] and the development of our technology.

During March 2012, the Company placed the first commercial MelaFind[®] systems in the U.S. and Germany, and intends to continue with a controlled launch of MelaFind[®] in selected U.S. and European markets.

[Table of Contents](#)

In August 2011, the Company received the International Organization for Standardization ("ISO") 13485 certification of the Company's comprehensive management system for the design and manufacture of medical devices. In September 2011 the Company received Conformance Européenne ("CE") Mark approval for MelaFind[®]. With CE Mark approval, the Company has the ability to market MelaFind[®] to dermatologists across the European Union and in certain other countries.

The Company received written approval from the FDA for the MelaFind[®] PMA application on November 1, 2011. As a condition of PMA approval, the Company committed to conduct 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[®].

In the first quarter of 2012, the Company supported MelaFind[®] pre-launch studies conducted by selected dermatologists in the U.S. and Germany. Enhancements to MelaFind[®] were effected relating to information gathered in these pre-launch studies, leading to the first commercial MelaFind[®] systems being placed in the U.S. and Germany during March 2012.

Prior to the commercial launch of MelaFind[®] in the first quarter of 2012, the Company had not generated any revenues from MelaFind[®].

The Company anticipates that it will continue to incur net losses for the foreseeable future in the commercialization of the MelaFind[®] device and the further development of MelaFind[®] and the Company's technology. We believe that period-to-period comparisons of our results of operations may not be meaningful and should not be relied on as indicative of our future performance.

Liquidity and Capital Resources

In 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 subject to various conditions for individual sales, including dollar, timing, and trading volume limitations, a minimum market per share price, and other contractual and regulatory requirements.

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

The Company did not sell any stock to Kingsbridge Capital Limited under the CEFF in the three months ended March 31, 2012 and March 31, 2011, respectively. As of March 31, 2012, 1,095,315 shares of common stock remain available for sale under the CEFF, exclusive of the 200,000 outstanding warrants held by Kingsbridge. Legal, accounting, and other costs associated with this agreement approximating \$62 have been deferred and this remaining balance will be charged to equity as a reduction of future proceeds from the CEFF or operations should management decide to abandon the CEFF which is set to expire in May of 2012.

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. The gross proceeds to the Company from the sale of the common stock totaled \$16.5 million. After deducting the underwriters' discounts and commissions and other offering expenses, net proceeds were approximately \$15.2 million. This offering closed on July 6, 2010.

[Table of Contents](#)

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 Securities and Exchange Commission (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 remains available under the Company's 2010 shelf registration statement as of March 31, 2012.

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 expenses.

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

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

As of March 31, 2012, the Company's total of cash and cash equivalents was approximately \$22.3 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 raise additional financing in the future. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term. In the event that the Company is unable to raise additional funds, the Company has the ability and intent to reduce certain discretionary expenditures.

Our cash and cash equivalents at March 31, 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 (in thousands)

Net cash used in operations was \$5,317 for the three months ended March 31, 2012. For the corresponding period in 2011, net cash used in operations was \$4,472. In both periods, cash used in operations was attributable to net losses after an adjustment for non-cash charges related to depreciation/amortization and share-based compensation, the acquisition of MelaFind[®] consumables inventory and other changes in operating assets and liabilities.

Cash Flows from Investing Activities

For the three months ended March 31, 2012, there was \$408 net cash used in our investing activities, for the purchase of \$82 in fixed assets and \$326 in components to be used by our contract manufacturers in the production of MelaFind[®] systems. For the corresponding period in 2011, \$8 net cash was used in our investing activities, principally for the purchase of fixed assets.

[Table of Contents](#)

Cash Flows from Financing Activities

For the three months ended March 31, 2012, there was \$29 provided by our financing activities representing the net of additional costs from our 2011 public offering and the proceeds from the exercise of stock options. For the three months ended March 31, 2011, no net cash was provided by 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 March 31, 2012, we had an accumulated deficit of approximately \$125.3 million. We anticipate that we will continue to incur net losses for the foreseeable future as we proceed with the MelaFind[®] commercialization process and expand our corporate infrastructure. We do not expect to generate significant product revenue until after we successfully commercialize MelaFind[®]. However, we will need substantial funds to broaden the commercial expansion of MelaFind[®], including development of a direct sales force and expansion of our contract manufacturing capacity. The timing and amount of any additional funding the Company may require to broaden the commercial expansion 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 and the interest we earn on these balances 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 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;
- the amount of direct payments we are able to obtain from physicians utilizing MelaFind[®];
- the costs of maintaining regulatory approval;
- reimbursement amounts for the use of MelaFind[®] that we are able to obtain from Medicare and third party payers;
- the 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 inventory 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;

[Table of Contents](#)

- 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 March 31, 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	\$ 2,217	\$ 437	\$ 943	\$ 837

Our long-term obligations represent a non-cancelable operating lease for our laboratory, assembly, and office space. The lease on approximately 20,000 square feet of space expires in December 2016. In April 2012, the Company entered into an agreement, effective May 1, 2012, to amend the existing lease for laboratory, assembly and office space which runs through December 2016. This amendment increases the previously leased space by 1,700 square feet at an annual rental of \$22.

Results of Operations (in thousands)

In the first quarter of 2012, the Company supported MelaFind[®] pre-launch studies conducted by selected dermatologists in the U.S. and Germany. Enhancements to MelaFind[®] were effected based on information gathered in these pre-launch studies. The first commercial MelaFind[®] systems were placed in the U.S. and Germany during March 2012, and the applicable sales and cost of sales were recorded for the first time. 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 or general expenses. Sales and marketing efforts were increased in the first quarter of 2012 leading up to and subsequent to the commercial launch of MelaFind[®].

Three Months Ended March 31, 2012 Compared to Three Months Ended March 31, 2011

Sales

Revenue of \$11 and deferred revenue of \$17 were recorded in the three months ended March 31, 2012 as the Company commenced its controlled commercial launch of the MelaFind[®] product during March 2012. Prior to the 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 a fee for the placement of the MelaFind[®] system and 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 placement fee revenue over the term of the user agreement, which is generally 2 years.

[Table of Contents](#)

Cost of Sales

Costs of \$130 were recorded as associated with the realization of MelaFind[®] revenue and deferred revenue during the three months ended March 31, 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 sold, the cost of the system access cards, and depreciation costs of the MelaFind[®] system placed with the customer which remains the property of the Company. Certain manufacturing overhead costs associated with supporting the contract manufacturers of MelaFind[®] along with technical support and quality costs are also recorded to cost of goods sold.

Research and Development Expense

Research and development ("R&D") expenses experienced an overall decrease of \$141 or 5% in the three months ended March 31, 2012 below the comparable period a year earlier. This decrease was principally the decrease in R&D labor and materials at Askion in Germany of \$446 and the reclassification of certain post-launch expenses to general and administrative ("G&A") offset by an increase of \$384 in expenses related to clinical studies initiated in Germany prior to launch.

General and Administrative Expense

General and administrative expenses experienced an overall increase of \$824 or 34% for the three months ended March 31, 2012 above the comparable period a year earlier. Within G&A, marketing costs represented \$279 of the increase as compensation costs increased by \$139 with the expansion of our sales force, expenses for consulting in Germany increased by \$80 and expenses related to the American Academy of Dermatology conference increased by \$42.

Other year-to-year increases in general and administrative costs for the three months ended March 31, 2012 include computer supplies and maintenance costs of \$74, investor relations of \$49, \$43 in recruiting expenses and the classification as G&A of approximately \$368 medical affairs and regulatory expense which would have been classified as R&D if incurred prior to launch.

Interest Income

Interest income for the three months ended March 31, 2012 decreased to \$13 from \$21 in the comparable period of 2011. Interest income decreased as a result of the deterioration of interest rates and smaller cash balances during the period in 2012.

Other Income

Other income for the three months ended March 31, 2012 was the \$5 royalty minimum we earn each quarter from Kavon on the sale/licensing of our 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.

[Table of Contents](#)

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

Revenue Recognition

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. 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 generally charges an initial installation fee for each MelaFind[®] system which covers training, delivery and supplies. 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.

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.

[Table of Contents](#)

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 fiscal year beginning January 1, 2012. For the year ended December 31, 2011 and as of March 31, 2012, comprehensive loss was equal to net loss as the Company had no comprehensive income 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. 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 March 31, 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

[Table of Contents](#)

reported within the time periods specified in the SEC's rules and Form 10-Q, and that such information was accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 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, the parties filed a stipulation on October 19, 2011 in which plaintiff stated its intention to file a motion seeking leave to amend its complaint. Defendants withdrew the outstanding motion to dismiss the current Amended Complaint without prejudice to renew it at a later date. On November 18, 2011, plaintiffs filed their motion for leave to amend the consolidated amended complaint. On December 18, 2011, defendants filed an opposition to plaintiff's motion for leave to amend the consolidated amended complaint. On February 8, 2012, plaintiffs filed their reply to defendants' opposition to the motion. On March 16, 2012, plaintiffs filed a revised proposed second amended complaint. On March 30, 2012, defendants filed a surreply in further opposition to the motion. On April 16, 2012, plaintiffs filed a surreply in further support of the motion.

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.

[Table of Contents](#)

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 March 31, 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 three months ended March 31, 2012 was approximately \$5.8 million, and as of March 31, 2012, we had an accumulated deficit of approximately \$125.3 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 March 31, 2012 we had approximately \$22.3 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 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 expansion of MelaFind[®], including 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 inventory 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

[Table of Contents](#)

- 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.

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
10.1#	Production Agreement, dated as of January 6, 2012, by and between MELA Sciences, Inc and Askion GmbH.*
10.2#	Service Agreement, dated March 21, 2012, by and between MELA Sciences, Inc. and QUINTILES Commercial Germany GmbH.
31.1#	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2#	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1#	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.1#	Interactive Data File
#	Filed herewith
*	Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

[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: May 3, 2012

[Table of Contents](#)

EXHIBIT INDEX

Exhibit No.	Description
10.1	Production Agreement, dated as of January 6, 2012, by and between MELA Sciences, Inc and Askion GmbH.*
10.2	Service Agreement, dated March 21, 2012, by and between MELA Sciences, Inc. and QUINTILES Commercial Germany GmbH.
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
*	Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

ASKION PRODUCTION AGREEMENT

This Production Agreement ("this Agreement") dated as of January 6, 2012 (the "Effective Date"), is entered into by MELA Sciences, Inc. (f/k/a Electro-Optical Sciences, Inc.), a corporation organized and existing under the laws of the State of Delaware with its principal business address at 50 South Buckhout Street, Suite 1, Irvington, New York 10533 ("MELA") and Askion GmbH, a German Company with limited liability with its registered office at Gewerbepark Keplerstraße 17-19, D-07549 Gera, Federal Republic of Germany ("Askion"), each of which is individually referred to as a "Party" and both of which are sometimes collectively referred to as "Parties".

RECITALS:

A. MELA is a medical device company focused on the design, development and commercialization of MelaFind[®], a non-invasive, point-of-care instrument to assist in the detection of early melanoma. Askion has experience and expertise in the design, engineering, and manufacture of precision optics and related components for the health care industry.

B. Upon and subject to the terms and conditions of this Agreement, MELA desires to retain Askion's services to manufacture, integrate, and test certain components, assemblies and systems of MELA's product known as MelaFind[®].

ARTICLE I**MANUFACTURING AND TESTING OBLIGATIONS**

1.1 RESPONSIBILITIES. MELA is engaging Askion, and Askion agrees, pursuant to this Agreement to manufacture and test the MelaFind[®] Hand-held Imager (the "Imager") and the field phantom fixture for the Imager (the "Phantom Fixture"), as well as in certain cases the integrated finished product (the "Product") consisting of the Imager, the Phantom Fixture and the Cart Assembly (the "Cart"), all in accordance with the Product Specifications as set forth in Appendix I attached hereto (the "Product Specifications"). The Imager and Phantom Fixture (sometimes collectively hereinafter referred to as the "Matched Pair") and the Product shall be tested by Askion in accordance with Testing Procedures in Appendix II attached hereto (the "Testing Procedures"). The Product Specifications and the Testing Procedures may be modified pursuant to Section 1.4 below. The services to be rendered by Askion (i) with respect to the Imager and the Phantom Fixture are manufacturing, integration, testing, warehousing, packaging/crating, shipping, service and repair and (ii) with respect to the Product are manufacturing, integration, testing, warehousing, labeling, packaging/crating, shipping, field service & customer support, service and repair. These services are collectively referred to herein as the "Manufacturing and Testing Services." Both during the Term (as defined in Section 4.1) and following termination or expiration of this Agreement for any reason, Askion shall not supply the Product, or any component thereof, including the Imager and the Phantom Fixture to any third party. In addition, both during the Term (as defined in Section 4.2) and for a period of five years following termination or expiration of this Agreement for any reason, Askion shall not supply any product similar to the

Product (or any prototype thereof) of the same field of application or any similar service to any third party whatsoever. In no event, either during the Term or thereafter shall Askion utilize any intellectual property that would violate the terms of Article VI hereof, including without limitation any Inventions as defined in Article IV. All Product shall be produced with MELA's logo imprinted or molded thereon, as the relevant Product Specifications may require. Askion shall deliver to MELA a monthly status report with respect to its performance of the Manufacturing and Testing Services by electronic mail with such detail as set forth on Appendix III attached hereto or as MELA requests. Such Manufacturing and Testing Services shall comport with the timing and scheduling set forth on applicable MELA approved purchase orders. Askion will also provide inventory management of finished goods, MELA owned components and accessories at its facility as part of the warehousing services for MELA.

1.2 MANUFACTURING. This Agreement has been entered into on the basis that, subject to the terms of this Agreement, Askion will manufacture and sell to MELA the Matched Pairs and/or Products as required, and requested by MELA in such quantities of the Matched Pairs and/or Products as ordered by MELA pursuant to approved purchase orders. Askion will perform all work necessary to procure components and manufacture the Matched Pairs and/or Products in accordance with the Product Specifications unless specifically directed otherwise by MELA in writing.

1.3 COOPERATION. The Parties will cooperate and keep each other informed in a timely manner, including providing appropriate documentation, with respect to all activities directly related to this Agreement, including, without limitation, access to drawings, specifications, engineering change orders, software, supplier information, processes and material directly related to this Agreement. The Parties agree to respond to questions and requests for clarification and approvals promptly and to notify each other of any approval or reasons for rejection within 15 days of such approval or rejection. The Parties agree that MELA shall be entitled to have one representative on-site at Askion's Gera, Germany facility during regular business hours throughout the Term (as defined in Section 4.1 hereof), who will be permitted to inspect the Manufacturing and Testing Services.

1.4 MODIFICATIONS TO SPECIFICATIONS AND PROCEDURES. MELA reserves the right to request in writing changes to the Product Specifications and Testing Procedures at any time. Such changes shall be effected by Askion, and Appendices I and II hereto shall be amended accordingly, unless Askion reasonably determines in good faith that such changes are not feasible, in which case Askion shall so notify MELA promptly following MELA's request for such changes. Askion and MELA will work together in good faith to modify the requested changes so that they are feasible. The changes as finally agreed shall be documented in writing and Appendices I and II shall be amended accordingly. Askion will manufacture and test the Imager and the Phantom Fixture, and manufacture, test and integrate the Product, in each case to conform to all such modified Product Specifications and/or Testing Procedures. Askion may not change the design, processes, or procedures relative to the manufacture, testing or integration of the Product, Imager or Phantom Fixture including the materials or components thereof, in any respect without the prior written consent of MELA's Director of Operations. To the

extent that any modification to the Product Specifications and/or Testing Procedures reasonably warrants an adjustment to the pricing provided in Sections 1.7(a), 1.7(b) or 1.7(c) herein or time schedules, MELA and Askion agree to negotiate in good faith an equitable adjustment for all such changes resulting from such modification to the Product Specifications and/or Testing Procedures.

1.5 DELIVERY AND SHIPMENT.

(a) MELA shall deliver written packaging & shipping instructions for each Matched Pair and each Product. Askion shall not deliver the Product and/or the Matched Pairs later or substantially earlier than the dates indicated in the relevant purchase order or sales order. All Matched Pairs and Products shall be packed and crated by Askion in accordance with the packaging instructions set forth on Appendix III attached hereto (the "Instructions"). The Instructions may be modified by MELA in writing from time to time, with all deliveries to MELA to be FOB Askion's loading dock at its Gera, Germany facility, using third party logistics (3PL) specified by MELA. All risk of loss from the FOB point shall be borne by MELA. All freight costs and customs duties shall be borne by MELA and, if such costs are prepaid by Askion, such costs shall be listed separately in the invoices provided by Askion to MELA as set forth in Section 1.8 (b) hereof.

(b) As the sole European authorized representative for MELA with respect to the Product, Askion will be responsible for technical (not medical) field & customer support, including customer delivery, installation and training of the Product and its accessories. All field & customer support for the Product will be provided by Askion under the guidance and approval of the MELA's Director of Operations.

1.6 SCHEDULES AND SALES FORECASTS. During the Term, MELA and Askion will jointly develop production plans, manufacturing & test rates and scheduled deliveries based on the latest MELA sales forecasts. MELA and Askion will review every 3 months any and all changes or potential changes to the forecast versus the production plan. These changes can include but are not limited to, historical demand analysis, regulatory changes, new demographic product positioning, promotional plans, planned or unplanned customer demand, supply chain disruptions, component end of life and risk aversion/mitigation. This review and evaluation will be held every quarter and will be called the "Rolling 3 Month Forecast Review". The Parties agree that a mechanism for forecasting parts which require a long lead time will be established and agreed by the Parties. Any changes will be documented as "Meeting Minutes" and annotated in respective MELA purchase order amendments approved by both MELA and Askion. Askion shall use its best efforts to accommodate changes requested by MELA.

1.7 PRICING.

(a) The unit price for each Matched Pair (consisting of one Imager and one Phantom Fixture) shall initially be USD \$*** and shall include the manufacturing, integration, testing, packaging/crating and warehousing for each Matched Pair.

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

This initial unit pricing shall apply to the first *** (***) Matched Pairs purchased hereunder. Thereafter the unit pricing for each Matched Pair shall be adjusted in accordance with subsection (d) hereof and mutually determined and agreed to by the Parties, in good faith, and be set forth in a writing which shall be affixed to this Agreement and amend the terms of unit pricing herein. The applicable pricing shall be set forth in each MELA approved purchase order for Matched Pairs. Unit pricing will be further adjusted proportionately for any and all work-in-process assemblies (WIP), inventory and raw component materials (on hand inventory) which are the property of MELA and shall result in an upfront "discounted" unit price, the amount of which shall be agreed to by MELA and Askion.

(b) The fee for each Product integration shall initially be USD \$*** and shall include the integration, testing, packaging/crating, labeling and warehousing for such Product. This initial fee shall apply to any Product purchased hereunder which incorporates as components the first *** (***) Matched Pairs purchased by MELA hereunder. Thereafter the fee for each Product shall be adjusted in accordance with subsection (d) hereof and mutually determined and agreed to by the Parties, in good faith, and be set forth in a writing which shall be affixed to this Agreement and amend the terms of pricing herein. The applicable pricing shall be set forth in each MELA approved purchase order for the Product.

(c) The fee for field service & customer support, including customer delivery and installation of the Product and its accessories and customer training related thereto shall be USD \$*** for each installation or field visit. This initial fee shall apply to any Product purchased hereunder which incorporates as components the first *** (***) Matched Pairs purchased by MELA hereunder. Thereafter the fee for field service & customer support shall be adjusted in accordance with subsection (d) hereof and mutually determined and agreed to by the Parties, in good faith, and be set forth in a writing which shall be affixed to this Agreement and amend the terms of pricing herein.

(d) The Parties acknowledge that the US dollar amounts specified in subsections (a), (b) and (c) above are based on an exchange rate of USD\$1.38 per 1€ To the extent that the published exchange rate of US dollars per Euro on the date of invoicing MELA for the relevant item or service is within a range of USD \$1.20 to \$1.50, then the pricing shall remain the same. To the extent that the published exchange rate is outside of such range then the Parties agree to use the average of the published exchange rates for 10 consecutive days commencing on the date which is 5 days prior to the date the exchange rate falls outside of the range. The Parties also recognize that the pricing set forth in subparagraphs (a) through (c) hereof will be subject to numerous variables, including the relevant experience of the Parties in performing the services and agreements hereunder, and the implementation of cost saving techniques as described herein.

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

As the parties are able to quantify and agree on reasonable future estimates for the elements on which unit pricing is based, such estimates will serve as the basis for determining pricing for production beyond the initial pricing referenced in subsections (a) through (c) above.

The Parties will cooperate in good faith to reduce the costs of the unit pricing by methods such as obtaining alternate sources of materials, reducing the cost of materials from current suppliers, revising product specifications, and improving integration, manufacturing or test methods. The Parties shall mutually agree on all cost-reduction methods prior to their implementation, it being understood that quality shall not be compromised. In order to optimize the costs of production while maintaining optimal functionality of the Imagers, Phantom Fixtures and Products, MELA will provide design expertise and engineering support for such cost reduction efforts with a view toward maximal application of design for manufacturing principles. The Parties acknowledge that they are committed to seeking and achieving cost reductions from the initial unit pricing specified herein and throughout commercial production for the Term of this Agreement.

(e) Any rework or replacement activities which are required in connection with field service & customer support services for the Product will be evaluated by MELA and Askion on a case-by-case basis. Any related charges that are determined to be due to Askion for the rework or replacement field services will be submitted to MELA by Askion in the form of a quotation which quotation shall be reviewed and approved by MELA before any such rework or replacement activity is performed.

(f) Upon renewal of this Agreement, MELA and Askion may negotiate in good faith a pricing adjustment, provided however no increase in any of the pricing contained herein shall exceed 3% per year.

1.8 PAYMENT. (a) Upon shipment of each Matched Pair or Product, Askion shall invoice MELA for such Matched Pair or Product. MELA shall pay such invoices within 30 days of receipt thereof.

(b) Askion shall invoice MELA for prepaid shipping costs for the Matched Pairs shipped in accordance with MELA's instructions, and for Product shipped and delivered by Askion within the European continent, upon the determination by Askion of the actual shipping costs associated therewith. MELA shall pay such invoice within 30 days of its receipt thereof.

1.9 WARRANTY.

(a) Askion warrants that each Imager, Phantom Fixture and Product will be free from defective workmanship or materials for a period of one year from the date of shipment, and that Askion will remedy such defects through the timely repair or replacement of components deemed to have been defective. Shipping costs associated with the repair or replacement due to workmanship and materials under the warranty for any Imager, Phantom Fixture or Product will be borne by Askion.

(b) Askion further represents that it shall manufacture, integrate, test and provide field service & customer support, as required hereunder, for each Matched Pair or Product and perform all of its obligations under this Agreement (i) in strict conformity with the Product Specifications, the Testing Procedures, and the Manufacturing and Testing Services, and in accordance with this Agreement and with all applicable laws, rules and regulations and (ii) in accordance with the current good manufacturing practices (cGMP) applicable to the manufacturing of the Matched Pairs and Product as defined by Quality System Regulations (QSR) as promulgated under the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq, as amended and in compliance with ISO 13485 required by the Medical Device Directive (MDD) (93/42/EEC). Askion further warrants and represents that (a) its work hereunder shall be performed in a good and workmanlike manner and that the Matched Pair and Product will be free of any liens and encumbrances, (b) it has the requisite and necessary experience, all necessary licenses and permits, equipment, facilities and personnel to properly perform the Manufacturing and Testing Services, and (c) it is not a party to any other agreement that would in any way conflict with, or restrict, its ability to perform the Manufacturing and Testing Services.

1.10 FAILURE TO MEET THE SCHEDULE, PRODUCT SPECIFICATIONS OR TESTING PROCEDURES. MELA shall have the right to reject any Matched Pair or Product that is not in compliance with the Product Specifications and/or Testing Procedures or in conformity with the warranty obligations of Askion pursuant to Section 1.9 or any other provision of this Agreement. Within thirty (30) days of receiving a nonconforming shipment of a Matched Pair or Product, MELA shall provide Askion with written notice of such rejection stating the reasons for such rejection. Askion shall as promptly as practicable correct such nonconformity by repairing or remedying the defect or replacing the Matched Pair or Product, in each case at their sole cost and expense including shipping costs. If Askion is unable to provide corrected deliverables in accordance with the Product Specifications and/or Testing Procedures within 60 days of such written notice, then in addition to any other rights MELA may have hereunder or under applicable law, at its sole discretion, MELA may (a) extend the correction period, or (b) give written notice of termination of this Agreement (see Article IV). Payment for any Matched Pair or Product shall not constitute acceptance of any nonconforming or defective Matched Pair or Product.

1.11 PRODUCTION TOOLING AND TESTING EQUIPMENT. Upon execution of this Agreement, Askion shall provide to MELA a list of production tooling and testing equipment, together with the cost thereof, required for the manufacture, integration, and testing of the Matched Pair and Product. Upon written approval of such list by MELA, MELA, at its option, shall either purchase such production tooling and testing equipment and deliver such equipment to Askion or, instruct Askion to purchase such equipment and upon invoice from Askion, reimburse Askion for its actual and reasonable out of pocket costs related to the purchase, periodic maintenance, and calibration of such equipment. Should any production tooling or testing equipment require replacement, Askion shall request approval from MELA to replace such production tooling or testing equipment and, upon written approval from MELA's Chief Financial Officer, MELA shall be responsible for the cost thereof. MELA shall own and retain title forever to all production tooling and all testing equipment, including, without limitation, all environmental chambers, purchased or paid for by MELA at any time.

1.12 QUALITY ASSURANCE. Askion shall utilize record-keeping, inventory, and other policies and procedures that allow MELA to comply with U.S. Food and Drug Administration ("FDA") Quality System Regulations and comparable European standards for the production of medical devices, as well as with CE, ISO 13485, ISO 9001, UL, and similar standards, as set forth in Appendix IV attached hereto and made a part hereof, which sets forth the agreement between the Parties with respect to their respective responsibilities as to quality assurance obligations and both European Regulatory and US FDA requirements pertaining to the Imager, the Phantom Fixture and the Product. Askion shall use its best efforts to take all actions necessary to enable MELA to obtain and maintain US FDA and comparable International approvals of the commercial use of the Product.

1.13 PROCEDURES FOR DOCUMENTS. Appendix IV attached hereto and made a part hereof sets out the agreement between the Parties as to the procedures that shall be utilized for identification of each document created or modified by Askion pursuant to this Agreement in order to ensure that MELA retains final ownership of such documents, while Askion may still integrate these documents in its own quality control system. At least one version of each such document must have all of its text in the English language. Askion shall keep complete, accurate and authentic accounts, notes, data and records of work performed under this Agreement, including, without limitation, records pertaining to the methods and facilities used by it for the manufacture, integration, testing, packaging, labeling, warehousing, and shipping, and technical field service & customer support of the Matched Pair or the Product.

1.14 PLANT AND EQUIPMENT. Askion shall conduct all Manufacturing and Testing Services of the Matched Pair and the Product at its facility located at Gera, Germany, or such other facility as the Parties may agree. Askion shall maintain its facilities, including all equipment or machinery used by Askion in the Manufacturing and Testing Services, or otherwise required in connection with the services provided under this Agreement, in a state of repair and operating efficiency consistent with the requirements of the Product Specifications.

ARTICLE II

REGULATORY RESPONSIBILITY; INTELLECTUAL PROPERTY

2.1 REGULATORY APPROVALS. MELA shall undertake and be responsible for the procurement of any and all regulatory approvals and/or registrations and customs approval necessary for sale of the medical devices incorporating the Product (the "Devices"). MELA shall be responsible for complying with the U.S. Food, Drug and Cosmetic Act and European Medical Device Directive (MDD) (93/42/EEC) and the regulations promulgated there under for distribution of the Devices in the United States ("FDA Approval") and European Member States or other countries outside the United States (CE Certification or other national regulations). MELA will maintain a Quality

System, certified by a European Notified Body, in accordance with Annex II of the MDD and EN ISO 13485:2003, the European and International standard for medical device quality systems. Appendix IV attached hereto sets out a description of such policies and procedures. Askion shall cooperate with and use its best efforts to assist MELA in fulfilling the responsibilities set forth in this paragraph.

2.2 **ASKION'S QUALIFICATIONS.** Askion shall obtain and maintain in full force and effect during the Term compliance with all EU member states and US requirements, and other countries to be determined upon the mutual agreement of the Parties, and regulatory authority licenses, permits, registrations, and approvals required in order to manufacture the Matched Pair and the Product pursuant to the terms hereof. Askion shall be registered with the FDA as a medical device manufacturer as an ISO 13485 certified company and shall notify MELA of any change in that status during the Term of this Agreement. Should Askion lose its status as an FDA-registered medical device manufacturer or lose its ISO 9001 or ISO 13485 certification, it shall have a period of 90 days to have the certification reinstated and if not reinstated within this cure period, MELA may give written notice of termination of this Agreement (see Article IV).

2.3 **INTELLECTUAL PROPERTY: TRADEMARKS AND COPYRIGHTS.** MELA shall have the sole right to prepare, file, prosecute and maintain trademark and copyright applications or registrations or licensing rights thereof with respect to any product (including, without limitation, the Matched Pair and the Product or any product contained therein). All such applications and registrations shall be at MELA's expense. MELA shall retain ownership and/or licensing rights of these applications and registrations throughout the Term and in perpetuity. Askion shall from time to time, as MELA may deem necessary or appropriate, execute and deliver to MELA any and all documents of transfer or assignment relating to the Matched Pair and the Product and cooperate fully in obtaining whatever approval or product protection that MELA may deem desirable or appropriate.

ARTICLE III PRODUCT LIABILITY

3.1 **NOTICE OF PRODUCT LIABILITY CLAIMS.** Each Party shall notify the other promptly in writing of any product liability claim brought with respect to the Matched Pair or the Product based on alleged defects in the design, manufacture, packaging, or labeling of the Matched Pair or the Product or other adverse claim regarding the Matched Pair or the Product. Upon receiving such written notice, MELA shall assume and have sole control of the defense of any such claim, including the power to conduct and conclude any and all negotiations, compromises or settlements. Askion shall promptly comply with all reasonable requests from MELA for information, materials or assistance with respect to the conduct of such defense.

3.2 **NOTICE OF INVESTIGATION.** Askion and MELA shall promptly notify each other in writing of any potential or actual investigation or governmental activity relating to the Matched Pair or the Product.

3.3 **PRODUCT LIABILITY INSURANCE.** During the Term Askion shall maintain at its expense in full force and effect general comprehensive, product liability and business interruption insurance policies, naming MELA as an insured party, with reputable insurers acceptable to MELA at a minimum liability limit of two million U.S. dollars covering the Matched Pair and the Product.

ARTICLE IV

TERM AND TERMINATION; FORCE MAJEURE

4.1 **INITIAL TERM.** The initial term of this Agreement shall commence on the Effective Date and continue for three (3) years from the date thereof (the "Initial Term").

4.2 **EXTENSIONS** Following the Initial Term, this Agreement shall renew for successive three year periods (the "Renewal Term", and together with the Initial Term, the "Term"), unless either Party notifies the other in writing of its intent to terminate no later than one year prior to the end of the Initial Term or any Renewal Term (see Section 4.5).

4.3 **TERMINATION BY MELA.** MELA shall have the right to terminate this Agreement (i) pursuant to Sections 1.10 or 2.2 hereof, or (ii) if Askion fails to perform in accordance with this Agreement and fails to cure such default within thirty (30) days of written notice thereof. In the event of termination pursuant to this Section 4.3, Askion will be required to remove and ship to MELA at Askion's own expense, all materials, inventory, work in process, finished goods including the Matched Pair or the Product, tools, fixtures, equipment, drawings and documents previously purchased by MELA being kept under Askion's control at their or any other facility.

4.4 **TERMINATION BY ASKION.** Askion shall have the right to terminate this Agreement on written notice to MELA only if MELA has failed to make any payments required by this Agreement in the time provided therefore and following sixty (60) days' from written notice of such failure from Askion, MELA does not pay all delinquent sums in full; provided, however that this provision shall not apply to any amounts not paid which are disputed in good faith as being payable hereunder.

4.5 **TERMINATION BY EITHER PARTY.** In addition to their respective rights set forth in Sections 4.3 and 4.4, either Party hereto shall have the right to terminate this Agreement on written notice to the other Party under the following circumstances:

(i) by mutual agreement;

(ii) in the event that the other Party is declared insolvent, or bankrupt by a court of competent jurisdiction, or a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party, or such other Party shall make or execute an assignment for the benefit of creditors, or a receiver is appointed by a court of competent jurisdiction over all or a substantial portion of the other Party's assets and such receivership is not dismissed within 30 days of appointment, or

(iii) in the event of the issuance of a final order, decree or other action by any competent judicial authority or governmental agency (including, without limitation, the FDA) which restrains, enjoins or prohibits the sale or introduction into interstate and/or international commerce of the Matched Pair or Product and such restraint, injunction or prohibition is not vacated within 30 days thereafter.

Under all conditions of termination, both Parties will be bound by all secrecy and non-disclosure conditions of this Agreement in perpetuity.

Under 4.1, 4.2, 4.4 or 4.5 (i), (ii) or (iii) above, at non-renewal or termination Askion will be responsible to return to MELA all materials, inventory, work in process, finished goods including the Matched Pair or the Product tools, fixtures, equipment, drawings and documents previously purchased by MELA being kept under Askion's control at their or any other facility. Shipping of such goods shall be at MELA's expense.

4.6 SURVIVAL. The termination or expiration of this Agreement shall be without prejudice (a) to the rights of any Party to receive upon its request all payments accrued and unpaid, or all documents, data and deliverables not delivered, as of the date of such expiration or termination; (b) the rights and remedies of either Party with respect to any previous breach or default under any representation, warranty or covenant herein contained; and (c) rights under any other provision of this Agreement which expressly and necessarily calls for performance after expiration or termination.

4.7 FORCE MAJEURE. If the performance of this Agreement or of any obligation hereunder is prevented, or restricted or interfered with by reason of any event of Force Majeure, the Party so affected, upon prompt notice (stating therein the nature of the suspension of performance and reasons therefore) to the other Party, shall be excused from performance, but only for the duration of such inability, provided that the Party so affected shall use its best efforts to avoid or remove such causes of nonperformance, and shall continue performance hereunder with the utmost dispatch whenever such causes are removed. Under no circumstances shall a Force Majeure event relieve either Party of any obligation hereunder for a period of more than ninety (90) days. "Force Majeure" shall mean acts of God, natural disasters, acts of civil or military authority, government priorities, fire, floods, epidemics, quarantine, energy crises, war or riots.

ARTICLE V

INDEMNIFICATION

5.1 ASKION'S INDEMNITY. Askion agrees to indemnify, defend and hold harmless MELA, its affiliates, directors, officers, employees, agents and customers, from and against any claims, liabilities, loss or expenses, including reasonable attorney's fees, arising out of or in connection with the failure of Askion to perform any of its obligations hereunder or the failure of a Matched Pair or Product delivered hereunder to comply with Askion's warranties in Section 1.9, including but not limited to any actual or alleged injury, damage, death or other consequence occurring to any person as a result, directly or indirectly, of such failure, regardless of the form in which such claim is made.

5.2 MELA's INDEMNITY. MELA agrees to indemnify, defend and hold harmless Askion, its affiliates, directors, officers, employees, agents and customers, from and against any claims, liabilities, loss or expenses, including reasonable attorney's fees, arising out of or in connection with the marketing, distribution or use of the Matched Pair or Product or the device into which the Matched Pair or Product is incorporated which is not the result of or related to Askion's failure to comply with its warranty obligations under Section 1.9 hereof, including but not limited to any actual or alleged injury, damage, death or other consequence occurring to any person as a result, directly or indirectly, of such failure, regardless of the form in which such claim is made.

5.3 PROCEDURES. Each indemnified party agrees to give the indemnifying party prompt written notice of any claims, including any claims asserted or made by any governmental authority, for which the other might be liable under the foregoing indemnification, together with the opportunity to defend, negotiate and settle such claims. Such notice shall be given to the indemnifying party promptly after receipt of such claim. Failure to provide or promptly provide such notice shall not release the indemnifying party from any of its obligations hereunder except to the extent that the indemnifying party is materially prejudiced by such failure. Each indemnified party will cooperate fully with the indemnifying party in defending or otherwise resolving any such action, and each indemnified party in any such action may at its option and expense be represented in such action. No party shall be responsible or bound by any settlement made by any other party without its prior written consent, provided that such any such party requested to give consent shall not unreasonably withhold its consent to any such settlement.

ARTICLE VI

TECHNOLOGY OWNERSHIP; CONFIDENTIALITY

6.1 TECHNOLOGY OWNERSHIP. Unless specifically and expressly granted herein, no licenses or rights under either Party's intellectual property rights are implied or granted in this Agreement. Each Party shall retain full ownership of all its intellectual property in existence prior to the date the Parties first entered into an agreement relating to the Matched Pair and Product or developed as a result of work outside the scope of this Agreement including without limitation that Production Agreement between MELA and Askion, dated as of January 25, 2006 (the "Prior Agreement"). MELA shall have full ownership, with no rights of ownership vested in Askion, of all inventions and discoveries, including any patent or other intellectual property rights (collectively, the "Inventions"), whether or not patentable, made by Askion or its employees (or any other third-party) in the course of performing any work under this Agreement, including, but not limited to, the Manufacturing and Testing Services, and the Prior Agreement, whether such Inventions were made by Askion alone or Askion and any other third party or Askion and MELA jointly. In the event that this Agreement shall be found by a court of competent jurisdiction not to vest full ownership of the Inventions in MELA, Askion hereby irrevocably assigns to MELA the sole and exclusive right, title and interest in and to all Inventions, including all rights thereunder and relating thereto, in perpetuity and without further consideration. In the event that any such patents are obtained by MELA, Askion shall be automatically licensed to practice the patented inventions(s) pursuant to

and only within the scope of this Agreement; provided, that nothing in this Agreement shall be construed to grant Askion a license to practice any such patented invention(s) beyond the scope of this Agreement. MELA, in its sole discretion, shall determine whether or not to obtain patent protection for such inventions or discoveries. Askion agrees, and agrees to cause its employees, to execute all agreements, instruments or filings determined by MELA to be necessary to document its ownership of any such inventions. The law of inventorship of the United States shall apply to any inventions whether made inside or outside the United States; provided, however, that to the extent Askion is obligated to pay any fee, tax or other similar charge under German inventorship law as a result of the work performed by Askion or its employees hereunder, MELA shall reimburse Askion for such fees, taxes and charges up to a maximum of \$5,000 without preapproval by MELA.

6.2 CONFIDENTIALITY. The Parties shall keep, and shall cause all of their employees, officers and directors to keep, the existence and terms of this Agreement confidential. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that during the Term and thereafter the receiving Party shall keep confidential and shall not publish, make use of or otherwise disclose to a third party or use for any purpose other than as provided for in this Agreement any information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "Confidential Information"), except to the extent that it can be established by the receiving Party by competent proof that such Confidential Information:

(i) was already known to the receiving Party as shown by its written records, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

(iv) was lawfully disclosed to the receiving Party, other than under an obligation of confidentiality, by a third party who had no obligation to the disclosing Party not to disclose such information to others.

Notwithstanding the foregoing, each Party may disclose the other's Confidential Information and the existence and terms of this Agreement to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations (including, without limitation, regulations promulgated by the U.S. Securities and Exchange Commission) or conducting pre-clinical or clinical trials, provided that if a Party is required by law or regulation to make any such disclosure of the other Party's Confidential Information it will give reasonable advance notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information required to be disclosed.

6.3 SURVIVAL. Sections 6.1 and 6.2 hereof shall survive the termination or expiration of this Agreement.

ARTICLE VII
MISCELLANEOUS

7.1 NOTICES. Any notices required or permitted to be given to a Party hereunder shall be in writing and delivered or sent to such Party at its address given below:

(i) if to Askion:

Askion, GmbH.
Gewerbepark Keplerstraße 17-19
D-07549 Gera
Germany
Attn: Lutz Doms
Telephone: + 49 (0) 365 7353 - 401
Facsimile: + 49 (0) 365 7353 - 402

(ii) if to MELA:

MELA Sciences, Inc.
50 South Buckhout Street, Suite 1
Irvington, New York 10533-2204
Attn: Richard I. Steinhart
Telephone: (914) 591-3783, Ext. 736
Facsimile: (914) 591-3701

With a copy to:

Golenbock Eiseman Assor Bell & Peskoe LLP
437 Madison Avenue
New York, NY 10022
Attn: Valerie A. Price, Esq.
Telephone: (212) 907-7335
Facsimile: (212) 754-0330

or such other address as such Party may hereafter specify; and shall be deemed given (i) when personally delivered to such Party; (ii) when transmitted by telecopy and receipt of such transmission is confirmed by telecopy; or (iii) when delivery is confirmed by an established overnight courier service.

7.2 ATTORNEYS' FEES. In the event of any litigation, arbitration, judicial reference or other legal proceeding involving the Parties to this Agreement to enforce any provision of this Agreement, to enforce any remedy available upon default under this Agreement, or seeking a declaration of the rights of either Party under this Agreement, the prevailing Party shall be entitled to recover from the other such attorneys' fees and costs as may be

reasonably incurred, including the costs of reasonable investigation, preparation and professional or expert consultation incurred by reason of such litigation, arbitration, judicial reference, or other legal proceeding.

7.3 ASSIGNMENT. Neither Party shall assign or transfer this Agreement or any of its rights or duties hereunder to a third party without the prior written consent of the other Party hereto; provided, however, that MELA shall be permitted to assign this Agreement to any third party in connection with the sale of its business, whether such sale is consummated as a sale of all or substantially all of the assets of MELA, a merger, consolidation or similar transaction, the sale of the capital stock of MELA or any other similar transaction. Any purported assignment or transfer in violation of this Section shall be void ab initio and of no force or effect.

7.4 GOVERNING LAW. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the principles of conflicts of laws of such State.

7.5 MEDIATION; SUBMISSION TO JURISDICTION; VENUE. The Parties agree to attempt to resolve any dispute, claim or controversy arising out of or relating to this Agreement first by mediation, which shall be conducted under the then current mediation procedures of The CPR Institute for Conflict Prevention & Resolution or any other procedure upon which the parties may agree. The parties further agree that their respective good faith participation in mediation is a condition precedent to pursuing any other available legal or equitable remedy, including litigation, arbitration or other dispute resolution procedures.

Either party may commence the mediation process by providing to the other party written notice, setting forth the subject of the dispute, claim or controversy and the relief requested. Within ten (10) days after the receipt of the foregoing notice, the other party shall deliver a written response to the initiating party's notice. The initial mediation session shall be held within thirty (30) days after the initial notice. The parties agree to share equally the costs and expenses of the mediation (which shall not include the expenses incurred by each party for its own legal representation in connection with the mediation).

The parties further acknowledge and agree that mediation proceedings are settlement negotiations, and that, to the extent allowed by applicable law, all offers, promises, conduct and statements, whether oral or written, made in the course of the mediation by any of the parties or their agents shall be confidential and inadmissible in any arbitration or other legal proceeding involving the parties; provided, however, that evidence which is otherwise admissible or discoverable shall not be rendered inadmissible or non-discoverable as a result of its use in the mediation.

Each Party consents to the exclusive jurisdiction and venue of the State of New York in respect of any mediation, and in the event mediation is not successful, of the federal and state courts located in New York in any action arising out of or relating to this Agreement, waives any objection it might have to jurisdiction or venue of such forums or that the forum is inconvenient, and agrees not to bring any such action in any other jurisdiction or venue to which either Party might be entitled by domicile or otherwise.

Notwithstanding anything to the contrary herein, the Parties agree that the requirements to submit to mediation herein shall not prohibit any Party from seeking immediate injunctive relief in connection with any dispute, claim or controversy in order to prevent irreparable harm.

7.6 ENTIRE AGREEMENT. This Agreement shall constitute the entire agreement between the Parties and shall supersede any other agreements, whether oral or written, expressed or implied, as they pertain to the subject matter hereof (including, but not limited to, that Production Agreement between the MELA and Askion dated as of January 25, 2006). The whole of this Agreement including all Annexes and Appendices attached hereto are to be taken together so as to give effect to every part thereof to the maximum extent practicable, with each document helping to interpret the other.

7.7 RELATIONSHIP. The relationship created by this Agreement shall be strictly that of independent contractors and shall not constitute a partnership, joint venture or agency. Neither Party is hereby constituted an agent nor legal representative of the other Party for any purpose whatsoever and is granted no right or authority hereunder to assume or create an obligation, expressed or implied, or to make any representation, warranties or guarantees, except as are expressly granted or made in this Agreement. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

7.8 WAIVER. The Parties mutually agree that a waiver by either Party of any right hereunder or the failure to perform or breach of any of the terms of this Agreement by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party.

7.9 SEVERABILITY. The illegality, invalidity or unenforceability of any provision (or any part thereof) of this Agreement shall not affect or limit the legality, validity or enforceability of any other provision or the other parts of such provision as the case may be, provided the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby. In lieu of any such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

7.10 COUNTERPARTS. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, authorized representatives of the Parties have affixed their signatures as of the date first written above.

MELA Sciences, Inc.

50 S. Buckhout Street, Suite 1
Irvington, NY 10533 USA

Signature:
/s/ Joseph V. Gulfo

Joseph V. Gulfo
President/Chief Executive Officer
On this 11 day of January 2012

Askion GmbH

Gewerbepark Keplerstrasse
D-07549
Gera, Germany

Signature:
/s/ Lutz Doms

Lutz Doms
Managing Director
On this 11 day of January 2012

SERVICE AGREEMENT

BETWEEN

QUINTILES Commercial Germany GmbH

registered address at

Schildkrötstrasse 17-19, D-68199 Mannheim, Germany

hereinafter "QUINTILES"

and

MELA Sciences Inc.

registered address at

50 South Buckhout St., Irvington, NY 10533, USA

hereinafter "MELA"

INDEX:

1.	SCOPE OF AGREEMENT	3
2.	QUINTILES OBLIGATIONS	3
3.	MELA OBLIGATIONS	4
4.	MUTUAL OBLIGATIONS	4
5.	PRICE AND PAYMENT	5
6.	LIABILITY AND INDEMNITY	5
7.	CONFIDENTIALITY	6
8.	DURATION AND TERMINATION	6
9.	NON-SOLICITATION	7
10.	RETURN OF MATERIALS	8
11.	COOPERATION AND GOVERNANCE	8
12.	OWNERSHIP AND INVENTIONS	8
13.	NOTICES	9
14.	ASSIGNMENT AND SUB CONTRACTING	9
15.	SURVIVAL	9
16.	ENTIRE AGREEMENT	9
17.	AMENDMENTS	9
18.	JURISDICTION	10

1. SCOPE OF AGREEMENT

- 1.1. MELA wishes to appoint QUINTILES and QUINTILES hereby accepts such appointment to perform the Services as described in Schedule I and II in accordance with the terms and conditions that are agreed hereinafter.
- 1.2. MELA commits to pay to QUINTILES the QUINTILES Service Fees in accordance with the payment schedule and terms of payment as described in Schedule II and to comply with the MELA obligations as particularly set out in clause 3. of this Agreement.

2. QUINTILES OBLIGATIONS

It is agreed that QUINTILES shall:

- 2.1. undertake all reasonable endeavours to deliver the Services as described in detail in Schedule I to this Agreement;
- 2.2. have the Services carried out by qualified pharmaceutical representatives according to §75 AMG (Arzneimittelgesetz – German Medicines Act) – as far as the detailing of medicines in the sense of §2 Clause 1 and Clause 2 No. 1 AMG are subject of the Services;
- 2.3. ensure that the provided QUINTILES personnel are familiar with the provisions of relevant legislation, codes of practice or guidelines applicable for the project;
- 2.4. manage all contractual obligations in respect of the employment of the QUINTILES Personnel including the payment of all salaries, QUINTILES bonuses and benefits;
- 2.5. be responsible for the management of the QUINTILES personnel. In conformance with QUINTILES policy, QUINTILES shall provide appropriate employee counseling and discipline, up to and including termination, to QUINTILES personnel who violate employment rules and who are otherwise underperforming their job responsibilities. QUINTILES will promptly follow-up on any reports made by MELA of a QUINTILES personnel non-compliance or underperformance and will apply such counseling or discipline as may be warranted in QUINTILES's sole judgment
- 2.6. ensure that the QUINTILES personnel will comply with all processes and procedures put in place by MELA, the marketing authorisation holder of the Product, for the reporting of adverse events and for responding to scientific questions raised by physicians;
- 2.7. inform MELA about the status of the Services performed on a regular basis throughout the entire duration of the project.

3. MELA OBLIGATIONS

Throughout the duration of this Agreement MELA hereby agrees that MELA shall:

- 3.1. pay the QUINTILES Service Fees in full and in accordance with the payment terms as set out in Schedule II to this Agreement;
- 3.2. provide QUINTILES with an adequate level of training and knowledge that is necessary to carry out its duties and to provide the Services; specifically MELA shall be responsible for the training of the QUINTILES personnel on disease areas and product knowledge;
- 3.3. be responsible for putting in place the processes and procedures necessary to ensure that adverse events are reported as required to MELA and to the relevant Authorities in accordance with the regulations by law (AMG – German Medicines Act / MPG – German Medical Devices Act) and that a scientific service is available to respond to scientific questions raised by physicians;
- 3.4. provide QUINTILES with marketing support and marketing materials to be used for the detailing of the products, with product samples (if applicable) and with ongoing sales data;
- 3.5. ensure that all provided marketing material is in accordance with applicable legal requirements and that the over-all Promotional Program shall not require or encourage any one or more of the QUINTILES personnel to offer, pay, solicit or receive any remuneration from or to physicians to induce referrals or purchase of the MELA Product.
- 3.6. ensure that all requisite licenses, approvals, permissions and consents necessary for the legitimate promotion, marketing, sales and distribution of the Product are in place throughout the duration of this Agreement;
- 3.7. have the right to instruct and access the QUINTILES personnel for all medical and scientific information on the product and product related matters;
- 3.8. ensure that MELA's relevant personnel are fully briefed as to the role of QUINTILES in order to enable smooth communication in the course of the project.
- 3.9. to inform the QUINTILES Project Manager at least three months prior to the agreed project end with a binding confirmation in writing, if MELA intends to take over QUINTILES employees at the end of the project term.

4. MUTUAL OBLIGATIONS

QUINTILES and MELA hereby agree:

- 4.1. that the QUINTILES Project Manager shall be informed immediately if MELA should not be satisfied with the delivery of the Services or find deficiencies; QUINTILES shall immediately implement suitable measures to resolve the problems;

-
- 4.2. to decide upon an extension of the project the latest three months prior to the agreed project end as set out in Schedule I;
 - 4.3. to inform the respective other party immediately if any Product Risks or Adverse Events become known to either party;
 - 4.4. that each party will appoint a responsible Project Manager who shall be the primary point of contact during the term of this agreement (see Schedule I)
 - 4.5. to carry out the Services in compliance with all relevant laws, rules and regulations applicable under the jurisdiction of Germany in which the Services are performed and to ensure that all personnel involved in the Services are familiar with and comply with the provisions of any such laws, rules and regulations.

5. PRICE AND PAYMENT

The prices, payment schedule, pass through costs and terms of payment for the Services are specified in Schedule II and are important parts of this agreement.

6. LIABILITY AND INDEMNITY

- 6.1. If not ruled differently in clause 6.2 QUINTILES will have unlimited liability for damages according to the relevant legal regulations of the German law.
- 6.2. QUINTILES shall not be liable for the slight negligence of minor obligations resulting from this Agreement. Neither QUINTILES, nor any of QUINTILES' directors, officers, employees, subcontractors or agents shall have any liability of any type (including, but not limited to, contract, negligence, and tort liability), for any loss of profits, opportunity or goodwill, or any type of indirect or consequential damage or loss in connection with or arising out of this Agreement, or the Services performed by QUINTILES hereunder. In addition, in no event shall the collective, aggregate liability (including, but not limited to, contract, negligence and tort liability) of QUINTILES under this Agreement exceed the amount of Service Fees actually payable to QUINTILES. Nothing herein is intended to exclude or limit any liability for willful misconduct or any liability for death or personal injury caused by negligence.
- 6.3. MELA shall hold harmless and protect QUINTILES against all damage claims and connected costs raised by third parties in the frame of the Services if they are raised in connection with the products of MELA or the materials provided by MELA. This does not hold if the damage with the third party was caused intentionally or grossly negligent by QUINTILES. Over and above this, MELA is obliged to make adequate provisions to prevent and limit damages.

7. CONFIDENTIALITY

- 7.1. QUINTILES and MELA each undertake not to disclose or permit to be disclosed to any third party, or otherwise make use of or permit to be made use of, any confidential information which comes into its possession under this Agreement.
- 7.2. QUINTILES and MELA shall undertake to ensure that all information disclosed under this Agreement remains confidential to those personnel who require that information in order to carry out their obligations under this Agreement. QUINTILES shall ensure that all QUINTILES employees are made aware of the requirements of this Agreement.
- 7.3. The obligations of the parties in Clauses 7.1 and 7.2 shall not extend to any confidential information which:
- is or becomes generally available to the public otherwise than by reason of a breach by the recipient of the clauses above; or
 - is known to the recipient party and is at its free disposal prior to its receipt from the other; or
 - is subsequently disclosed to the recipient party by a third party who is not under the obligation of confidence; or
 - QUINTILES or MELA may be required to disclose under any statutory, regulatory or similar legislative requirements subject to the imposition of the obligations of secrecy wherever possible in that relationship; or
 - is disclosed by QUINTILES to a third party to such extent only as is necessary for the purposes of this Agreement and subject to QUINTILES using all reasonable endeavours to ensure that the person in question keeps the same confidential and does not use the same except for the purposes for which the disclosure is made.
- 7.4. The obligations of QUINTILES and MELA under this Clause 7 shall survive the termination for whatever reason of this Agreement for five years.

8. DURATION AND TERMINATION

- 8.1. This Agreement commences on the date of signature hereof and shall continue for the period specified in Schedule I, subject to early termination on notice in accordance with clause 8.2., 8.3., 8.4. or a mutual agreement on the extension of the project according to 4.2.
- 8.2. Either party shall have the right to terminate this Agreement if the other party commits any material breach of this Agreement, and, in the case of a breach capable of remedy, fails to remedy the same within thirty (30) days after receipt of a written notice giving particulars of the breach and confirming the intention to terminate if not remedied.
- 8.3. If either party shall become bankrupt or insolvent or if all or a substantial part of its business or assets shall be placed in the hands of a Receiver, Administrator,

Administrative Receiver, Liquidator, Trustee in Bankruptcy or similar officer or an insolvency practitioner, whether by its voluntary act or otherwise then this Agreement and the rights granted herein shall immediately be subject to termination at the option of the other party.

- 8.4. QUINTILES and MELA agree that MELA shall have the right of an early termination at will the earliest after 12 month project duration with a notice period of 3 months to the new effective termination date (e.g. giving notice on the 31st Dec. to terminate on the 31st March). In such a case MELA has to pay the full Quintiles Service Fees (Daily Rates) for all provided staff until the actual end of the project (the new effective termination date). If Quintiles is able to deploy members of the provided staff to a new QUINTILES Project prior to the new effective termination date, the obligation of MELA to pay the Daily Rates for such an individual will terminate at the date of their effective assignment to the new project.
- 8.5. Any termination of this Agreement shall not affect the accrued rights of either QUINTILES or MELA arising under or out of this Agreement and all provisions which expressly or by implication survive this Agreement; they shall remain in full force and effect.

9. NON-SOLICITATION

- 9.1. MELA hereby undertakes to QUINTILES that at no time during the Project Term MELA and/or any of its Affiliates shall:
- (a) make any offer of employment or enter into any discussions or negotiations with a view to making any offer of employment to any person employed by QUINTILES in providing all or any part of the Services hereunder ("**Relevant Employee**"); or
 - (b) solicit or attempt to solicit services from any Relevant Employee on their own account or entice or attempt to entice any Relevant Employee away from QUINTILES; or
 - (c) have business dealings with or attempt to have business dealings with any Relevant Employee (other than pursuant to this agreement).
- 9.2. In the event that any Relevant Employee providing any of the Services referred to herein should accept employment with MELA, or any of its Affiliates, during the term of their respective Assignments and/or during the Project Term (including any extensions thereof), or start to provide services to MELA, or any of its Affiliates, the same as or similar to the Services either as an individual or through a third party during the term of their respective Assignments under this Agreement (including any extensions thereof), QUINTILES will charge and MELA will pay a Take-on Fee of 25% of the annual contracted basic salary or fee offered to such Relevant Employee upon commencement of their employment at MELA or any of its Affiliates.

9.3. For the avoidance of doubt no Take-on Fee shall be payable by MELA upon the date of expiry of the agreed Project Term (as referred to in Schedule I) or, if extended, upon the date of expiry of any such extension to the Project Term.

10. RETURN OF MATERIALS

QUINTILES shall within 30 days of termination of this Agreement at the request of MELA destroy or return at the expense of MELA all materials belonging to MELA other than those which QUINTILES has an obligation to archive. Nothing in this Agreement shall be construed to transfer from MELA to QUINTILES any FDA or regulatory record-keeping requirements.

11. COOPERATION AND GOVERNANCE

- 11.1. All data and information in the possession of MELA or under his control necessary for QUINTILES to conduct the Services will be forwarded by MELA to QUINTILES. QUINTILES shall not be liable to MELA nor be deemed to have breached this Agreement for errors, delays or other consequences arising from MELA's failure to timely provide documents, materials or information. The cooperation between MELA and QUINTILES has to enable QUINTILES at all times to fulfil its contractual obligations in time and in full. If MELA, for reasons other than a breach by QUINTILES, delays an agreed starting date for the Services or suspends performance of the Services, QUINTILES reserves the right to maintain to claim its fees.
- 11.2. For the ongoing governance of the project QUINTILES and MELA agree to establish a Joint Steering Committee that should hold regular local meetings (e.g. every 3-4 months in Mannheim) to discuss and decide on all relevant business topics for the MELA sales activities in Germany. The Joint Steering Committee shall be formed by the MELA Project Leader, the QUINTILES Project Manager, the responsible QUINTILES Business Unit Director and the National Business Manager. Other relevant members of the MELA and Quintiles Management Staff could join the meetings as needed.

12. OWNERSHIP AND INVENTIONS

- 12.1. All MELA patents, trade secrets, copyrights, trade names, trademarks, service marks, proprietary data and materials or intellectual property and all improvements to any of the foregoing used in connection with the Services provided pursuant to this Agreement shall remain the sole and exclusive property of MELA and QUINTILES rights to use such MELA Property shall be limited to those permitted by this Agreement.
- 12.2. Notwithstanding the foregoing, MELA and QUINTILES agree that all QUINTILES property (including but not limited to certain analytical methods, procedures and techniques, manuals, financial information, technical expertise and software) or improvements thereto which are used, improved, modified or developed by QUINTILES under or during the term of this Agreement are the sole and exclusive property of QUINTILES.

13. NOTICES

Any notice or other communication to be given under this Agreement shall be in writing and delivered personally or sent by facsimile transmission or first-class registered mail.

14. ASSIGNMENT AND SUB CONTRACTING

14.1. This Agreement may not be assigned by QUINTILES or MELA to any third party without prior written consent of the other party, which will not be unreasonably withheld.

14.2. With prior written consent from MELA, which will not be unreasonably withheld, QUINTILES shall be entitled to use agents and sub-contractors to carry out the Services provided that QUINTILES will be responsible for the acts and omissions of such agents and sub-contractors as if the Services were performed by QUINTILES.

15. SURVIVAL

The rights and obligations of MELA and QUINTILES, which by intent or meaning have validity beyond termination or completion of this Agreement (including, but not limited to, rights with respect to confidentiality, liability and indemnity, ownership and inventions) shall survive the termination or completion of this Agreement.

16. ENTIRE AGREEMENT

This Agreement including all Schedules contains the entire understanding of the parties with respect to the subject matter herein, and supersedes all previous agreements (oral and written), negotiations and discussions.

17. AMENDMENTS

17.1 Any material amendment or change of the details of this Agreement (including, but not limited to, changes in an agreed starting date for the Services, the nature of the Services or the number of team members) must be in writing and executed by duly authorised representatives of MELA and QUINTILES. Both parties agree to act in good faith and promptly when considering a written amendment or change requested by the other party. The amendment shall not affect the accrued rights of either QUINTILES or MELA arising under or out of this Agreement and all provisions which explicitly or by implication survive this Agreement shall remain in full force and effect.

17.2 Where any provisions of this Agreement shall be invalid or impracticable, such invalidity or impracticability shall not affect any other provision hereof. In such case, QUINTILES and MELA agree to replace any invalid or impracticable provision by a valid and practicable provision that captures the meaning and purpose of the invalid or impracticable provision. The same goes for omissions in the agreement.

18. JURISDICTION

18.1. This Agreement shall be governed by the laws of Germany and is subject to the jurisdiction of the German Courts.

18.2. If both parties are going to settle any disputes by an arbitration process, this arbitration process shall be ruled according to the guidance of the American Chamber of Commerce in Germany (AmCham Germany) in Frankfurt.

18.3. No failure or delay on the part of QUINTILES or MELA to exercise or enforce any rights granted under this Agreement shall be interpreted or operate as a waiver thereof.

For and on behalf of QUINTILES Commercial Germany GmbH

Date:	<u>21 March 2012</u>	Signature:	<u>/s/ Peter Kurtz</u>
Signature:	<u>/s/ Monika Beintner</u>	Name:	<u>Peter Kurtz</u>
Name:	<u>Monika Beintner</u>	Function:	<u>Key Account Director</u>
Function:	<u>Managing Director</u>		

For and on behalf of MELA Sciences Inc.

Date:	<u>March 19, 2012</u>		
Signature:	<u>/s/ Joseph V. Gulfo</u>	Signature:	—
Name:	<u>Joseph Gulfo</u>	Name:	—
Function:	<u>President & CEO</u>	Function:	—

**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: May 3, 2012

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

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

I, Richard I. Steinhart, certify that:

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

Date: May 3, 2012

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

**MELA SCIENCES, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of MELA Sciences, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the period ended March 31, 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)
May 3, 2012

/s/ Richard I. Steinhart
Richard I. Steinhart
Senior Vice President & Chief Financial Officer
(Principal Accounting and Financial Officer)
May 3, 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.