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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 7, 2012**

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**MELA Sciences, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-51481**  
(Commission  
File Number)

**13-3986004**  
(IRS Employer  
Identification No.)

**50 South Buckhout Street, Suite 1  
Irvington, New York**  
(Address of principal executive offices)

**10533**  
(Zip Code)

**Registrant's telephone number, including area code (914) 591-3783**

(Former name or former address, if changed since last report.)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02 — Results of Operations and Financial Condition**

On November 7, 2012, MELA Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2012 and that it will hold a conference call to discuss such results. The press release is attached hereto as Exhibit 99.1.

This information shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 — Financial Statements and Exhibits**

(d) Exhibits

99.1 Press Release, dated November 7, 2012

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MELA Sciences, Inc.

Date: November 7, 2012

By: /s/ Richard I. Steinhart  
Richard I. Steinhart  
Sr. VP & Chief Financial Officer



### MELA Sciences Announces Third Quarter 2012 Financial Results

IRVINGTON, NY, November 7, 2012 — MELA Sciences, Inc. (NASDAQ: MELA), the medical device company that has developed and is commercializing MelaFind®, today announced financial results for the third quarter ended September 30, 2012.

#### Third Quarter 2012 Performance Highlights:

- Accelerated our rate of signed user agreements, system placements and the training of new customers in connection with our controlled and deliberate launch of MelaFind in the US and in several key cities throughout Germany.
  - Ended the third quarter with 45 MelaFind systems installed in dermatologists' offices in the US and Germany and continued to work with customers to train and assist them in using MelaFind appropriately to incorporate its use successfully into their practices.
  - Obtained signed user agreements for an additional 14 MelaFind systems in the US in the third quarter, all of which have been installed with associated revenue booked in October.
  - To date, signed user agreements for 99 MelaFind systems have been obtained, and 76 systems have been installed with associated revenue booked in the US and Germany.
- Expanded and enhanced our US sales presence.
  - Added three US territory managers with extensive dermatology sales experience in New York, California and Texas, for a total of 7 sales representatives in the US.
  - Established a team of dedicated Systems Operations Specialists to perform installations and to train new and existing customers.
- Expanded our International management team to support the acceleration of the MelaFind global launch.
  - Hired a highly experienced commercial head of operations in Germany, Austria and Switzerland and established offices in Munich as of November 1, 2012.
  - In the process of adding additional sales representatives and establishing technical support and training staff in Germany.
- Presented, published, and submitted additional data for publication:
  - US Pilot reader study demonstrating dermatologists elected not to biopsy 20% of melanomas in a subset of lesions from the pivotal trial, published in Archives of Dermatology.
  - Multiple presentations of German reader study demonstrating superior performance of dermatologists that incorporated the MelaFind result in biopsy

decision-making (only 3/101 dermatologists detecting 90% of melanomas without MelaFind information, versus 22/101 dermatologists detecting over 90% of melanomas with MelaFind information, at comparable specificity).

- Presentation of US resident reader study demonstrating improved melanoma detection after being provided with MelaFind result (54% baseline sensitivity increased to 77% sensitivity with MelaFind result).

- Received final approval for Post Approval Study from FDA, and preparing for study initiation.

“We have completed our first six months on the market with MelaFind, and are pleased to report that we have escalated the pace of our commercial activities, consistent with our planned deliberate and controlled launch of MelaFind in the US and Germany. We are thrilled with the level of demand we are experiencing and broad based clinician acceptance,” said Dr. Joseph V. Gulfo, President and CEO of MELA Sciences. “As of today, 99 dermatologists have signed user agreements, and MelaFind has been put into the offices of over 76 of these clinicians in the US and Germany. We are working alongside our customers to help them incorporate MelaFind into their practices, which we believe will, in turn, facilitate both accelerating utilization and wider penetration.”

“Based on favorable customer experiences, high levels of demand and the increasing cadence at which we have been signing user agreements and placing systems in the field, we believe we remain on track to achieve our stated goal of placing 200 systems in the US and 75 in Germany by the end of 1Q 2013,” Dr. Gulfo continued. “The only thing that marred an otherwise excellent quarter, which proceeded to overall plan, was not being able to book the revenue for 14 systems for which we obtained signed user agreements in the third quarter until they were installed in October. This resulted in revenues that were slightly below 2Q results and did not reflect the increased level of business activity that we saw in the third quarter.”

“We are honored that the Cleveland Clinic included MelaFind as one of ‘The Top 10 Medical Innovations for 2013.’ To be selected for inclusion into this group is a testament to the clinical and commercial potential for MelaFind. We are just starting to see the potential being realized in the clinical community, and anticipate further acceleration in utilization, which is very gratifying.” Dr. Gulfo concluded.

MelaFind is the Company’s breakthrough non-invasive and objective automated point of care system for use when a dermatologist chooses to obtain additional information for a decision to biopsy clinically atypical pigmented skin lesions with one or more clinical or historical characteristics of melanoma.

### **Third Quarter 2012 Financial Results**

Revenues for the three months ended September 30, 2012 were \$69,127 compared to no revenues reported for the same period in 2011. Deferred revenues reported as of September 30, 2012 were \$150,876 versus no deferred revenue for 3Q 2011. Revenues were based on the installation of 20 MelaFind systems in the third quarter and do not account for the revenue from 14 additional user agreements signed in the third quarter, which have been booked in the fourth quarter following installation in October. Deferred revenues reflect the timed recognition of the installation fee revenue over the term of the user agreement which is generally two years.

The Company’s net loss for the three months ended September 30, 2012 was \$5.4 million, or \$0.17 per diluted share, compared to a net loss of \$6.1 million, or \$0.24 per diluted share, for the same period in 2011. The decrease in the net loss was primarily attributable to a significant reduction in stock based compensation expenses that were incurred in third quarter 2012

versus the same period a year ago, but partially offset by an increase in General and Administrative expenses related to the expansion of the Company's sales force and the Company's incremental marketing costs as well as the increase in direct costs associated with the placement of MelaFind systems in dermatologists' offices.

As of September 30, 2012, the Company's cash and cash equivalents were \$13.3 million.

### **Conference Call**

MELA Sciences will host a conference call today at 4:30 PM EST to discuss third quarter 2012 quarterly results. To participate in the call, dial 1-877-303-9205 approximately 10 minutes before the conference call is scheduled to begin. To listen via live webcast, please go to the investor relations section of the MELA Sciences website at <http://www.melasciences.com> approximately 10 minutes prior to the teleconference start time. If you are unable to participate during the live conference call and webcast, the conference call audio cast will be archived and available for replay for approximately 90 days.

### **About MELA Sciences, Inc.**

MELA Sciences is a medical device company focused on the commercialization of its flagship product, MelaFind®, and its further design and development. MelaFind is a non-invasive tool to provide additional information to dermatologists during melanoma skin examinations. The device uses light from visible to near-infrared wavelengths to evaluate skin lesions up to 2.5 mm beneath the skin. The device provides information on a lesion's level of morphologic disorganization to provide additional objective information that may be used by dermatologists in the biopsy decision-making process. MelaFind has been approved by the US Food and Drug Administration for use in the US. In addition, MelaFind has received CE Mark approval and is approved for use in the European Union.

For more information on MELA Sciences, visit [www.melasciences.com](http://www.melasciences.com).

### **Safe Harbor**

This press release includes "forward-looking statements" within the meaning of the Securities Litigation Reform Act of 1995. These statements include but are not limited to our plans, objectives, expectations and intentions and other statements that contain words such as "expects," "contemplates," "anticipates," "plans," "intends," "believes," "assumes," "predicts" and variations of such words or similar expressions that predict or indicate future events or trends, or that do not relate to historical matters. These statements are based on our current beliefs or expectations and are inherently subject to significant known and unknown uncertainties and changes in circumstances, many of which are beyond our control. There can be no assurance that our beliefs or expectations will be achieved. Actual results may differ materially from our beliefs or expectations due to financial, economic, business, competitive, market, regulatory and political factors or conditions affecting the company and the medical device industry in general, as well as more specific risks and uncertainties facing the company such as those set forth in its reports on Forms 10-Q and 10-K filed with the US Securities and Exchange Commission (the "SEC"). Factors that might cause such a difference include whether MelaFind® achieves market acceptance. Given the uncertainties affecting companies in the medical device industry such as the Company, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. The Company urges you to carefully review and consider the disclosures found in its filings with the SEC which are available at [www.sec.gov](http://www.sec.gov) and [www.melasciences.com](http://www.melasciences.com).

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For further information contact:

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**TABLES TO FOLLOW**

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

	<u>September 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
	<u>(unaudited)</u>	<u>*</u>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 13,275,849	\$ 27,996,871
Accounts receivable	100,578	—
Inventory	656,560	—
Prepaid expenses and other current assets	619,495	1,061,550
<b>Total Current Assets</b>	<u>14,652,482</u>	<u>29,058,421</u>
Property and equipment, net	5,243,082	1,626,791
Patents and trademarks, net	50,283	59,208
Deferred financing costs	—	62,391
Deferred public offering cost	122,291	—
Other assets	71,985	586,498
<b>Total Assets</b>	<u>\$ 20,140,123</u>	<u>\$ 31,393,309</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable (includes related parties of \$54,750 and \$36,027- as of September 30, 2012 and December 31, 2011, respectively)	\$ 1,277,540	\$ 670,950
Accrued expenses	913,110	745,754
Deferred revenue (ST)	82,782	—
Other current liabilities	81,897	30,993
<b>Total Current Liabilities</b>	<u>2,355,329</u>	<u>1,447,697</u>
<b>Long Term Liabilities:</b>		
Deferred rent	142,383	138,216
Deferred revenue (LT)	68,094	—
<b>Total Long Term Liabilities</b>	<u>210,477</u>	<u>138,216</u>
<b>Total Liabilities</b>	<u>2,565,806</u>	<u>1,585,913</u>
<b>Stockholders' Equity</b>		
Preferred stock — \$.10 par value; authorized 10,000,000 shares; issued and outstanding: none		
Common stock — \$.001 par value; authorized 45,000,000 shares; issued and outstanding 31,323,910 shares at September 30, 2012 and 30,307,538 at December 31, 2011	31,324	30,308
Additional paid-in capital	153,664,419	149,304,424
Accumulated deficit	(136,121,426)	(119,527,336)
<b>Stockholders' Equity</b>	<u>17,574,317</u>	<u>29,807,396</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 20,140,123</u>	<u>\$ 31,393,309</u>

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



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

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

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

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