UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 6, 2011

MELA Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-51481**	**13-3986004**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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.)

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 — Other Events

On September 6, 2011, MELA Sciences, Inc. (the "Company") issued a press release announcing that it received CE Mark approval for MelaFind®, allowing the Company to market its MelaFind device to dermatologists across the European Union. A copy of the press release is attached as Exhibit 99.1 to this current report.

Item 9.01 — Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	MELA Sciences, Inc. Press Release, dated September 6, 2011

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 hereunto duly authorized.

MELA Sciences, Inc.

Date: September 6, 2011

By: /s/ Richard I. Steinhart
Richard I. Steinhart,
Chief Financial Officer
(Principal Financial Officer)

Exhibit 99.1

MELA Sciences Receives European Union Approval for MelaFind®

- Company Plans to Initially Launch MelaFind in Germany -

IRVINGTON, NY (September 6, 2011) – MELA Sciences (NASDAQ: MELA) today announced that it received CE Mark approval for MelaFind®, allowing the company to market its MelaFind device to dermatologists across the European Union (EU). The company intends to initially market MelaFind in Germany, which has the highest incidence of melanoma in Europe.

The CE (Conformité Européenne, or "European Conformity") Mark approval allows the company to market MelaFind freely across the 27 nations that comprise the EU. The EU is the world's largest economic bloc with over 500 million residents and annual economic output of over $16 trillion.

"We're extremely pleased to receive the CE Mark for MelaFind," said Joseph V. Gulfo, MD, President and CEO, MELA Sciences. "With more than 81 million people, Germany represents a significant opportunity for the company and an ideal market to launch MelaFind in the EU. Given the high rates of melanoma seen in the German population, we believe MelaFind has the potential to make a deep impact on the disease there. In order to achieve our initial goals for the commercial development phase of the launch, we plan to utilize a direct sales force that will focus on strategically placing MelaFind systems in the top dermatology practices in several key cities throughout the country."

Melanoma rates in Germany have doubled over the last decade and the national mortality rate from the disease is the highest in Europe. Over 20,000 Germans are expected to be diagnosed with melanoma by 2016. Germany is the only country in the world with a nationwide skin screening effort in place for men and women age 35 and older.

The clinical data for the CE Mark application were submitted in May 2011 and the complete technical file was submitted in early July 2011.

"We are very impressed with the process in obtaining EU regulatory approval, which included an extensive audit of our facilities," said Dr. Gulfo. "We enjoyed

frequent, straightforward and transparent interactions with European reviewers leading up to application submission and throughout the review process."

The studies used to support the CE Mark application were the 1,383-patient U.S. pivotal trial and the companion reader study of 110 dermatologists: the device demonstrated a 98% sensitivity; whereas dermatologists had a 72% sensitivity in the companion reader study. MELA Sciences worked with the U.S. Food and Drug Administration (FDA) to design the pivotal study, the largest ever conducted in melanoma detection, and has a Binding Protocol Agreement with the FDA. Approximately 11% of all lesions and melanomas in the MelaFind database were obtained from European clinical sites.

In the U.S., MELA Sciences submitted a PMA application for MelaFind in June 2009, and received a positive vote from the General and Plastic Surgery Devices Panel at an advisory committee meeting in November 2010. The company is currently awaiting the FDA's decision.

About MELA Sciences, Inc:

MELA Sciences is a medical technology company focused on developing MelaFind®, a non-invasive and objective multi-spectral computer vision system intended to aid in the detection of early melanoma. MELA Sciences designed MelaFind to assist in the evaluation of clinically atypical pigmented skin lesions, when a dermatologist chooses to obtain additional information before making a final decision to biopsy to rule out melanoma. MelaFind acquires and displays multi-spectral (from blue to near infrared) and reconstructed RGB digital images of pigmented skin lesions and uses automatic image analysis and statistical pattern recognition to help identify lesions to be considered for biopsy to rule out melanoma, the deadliest form of skin cancer. Although no cure is currently available for advanced-stage melanoma, melanoma is virtually 100% curable if caught early.

MelaFind® Proposed Indications for Use

MELA Sciences proposes that MelaFind® is indicated for the evaluation of clinically atypical cutaneous pigmented lesions (those having one or more clinical or historical characteristics of melanoma, such as asymmetry, border irregularity, color variegation, diameter greater than 6 mm, evolving, patient concern, regression, and "ugly duckling"), when a dermatologist chooses to obtain additional information before making a final decision to biopsy to rule out melanoma. MelaFind is a non-invasive and objective multi-spectral computer vision system designed as a tool to aid dermatologists in the detection of early (e.g., non-ulcerated, not bleeding, or less than 2.2 cm in diameter) melanoma.

MelaFind is not a screening device and is not indicated for non-pigmented lesions, banal pigmented lesions, lesions that are clinically identified as definite melanomas, or lesions on special anatomical sites (i.e., acral, mucosal, subungual).

Regulatory Status

MelaFind® has received the CE Mark and is approved for use in the European Union. The MelaFind Pre-Market Approval (PMA) application was filed with the FDA in June 2009,

received positive FDA Advisory Panel recommendations in November 2010 and is currently under review at the FDA. In February 2011, the company submitted an amendment to the MelaFind PMA application with the FDA, limiting the indication for use to dermatologists and in May 2011 the company submitted another amendment to the MelaFind PMA that incorporated a training program for users. MELA Sciences cannot predict either the timing of the FDA's decision on the PMA application or the outcome. FDA approval is required prior to marketing MelaFind in the United States.

For more information on MELA Sciences, visit 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 U.S. Securities and Exchange Commission (the "SEC"). Factors that might cause such a difference include whether the data from our pre-clinical studies and clinical trials is sufficient to support regulatory approval of MelaFind®, whether we are required to provide the FDA with additional data or perform additional testing on MelaFind or, even if we do receive regulatory approval, whether any such approval is for the indications we seek. 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 and www.melasciences.com.

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