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 26, 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 26, 2011, MELA Sciences, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has issued an Approvable Letter for the MelaFind® Pre-Market Approval (PMA) application. The Company intends to work with the FDA to finalize the physician and patient labeling, package insert, user's guide, training program and clinical protocol for a post-approval study in order to obtain final approval. 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 26, 2011

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: September 26, 2011

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

Exhibit 99.1

MELA Sciences Receives Approvable Letter from FDA for MelaFind®

- Company to finalize labeling, training program and clinical protocol for post-approval study -

- Conference call scheduled for 8:30 a.m. -

IRVINGTON, NY (September 26, 2011) — MELA Sciences (NASDAQ: MELA) today announced that the U.S. Food and Drug Administration (FDA) has issued an Approvable Letter for the MelaFind® Pre-Market Approval (PMA) application. The company intends to work with the agency to finalize the physician and patient labeling, package insert, user's guide, training program and clinical protocol for a post-approval study in order to obtain final approval.

"The FDA's Approvable Letter for MelaFind represents a monumental milestone for MELA Sciences and the millions of Americans who are at risk of developing melanoma, the deadliest form of skin cancer," said Joseph V. Gulfo, MD, President and CEO, MELA Sciences. "The company has worked tirelessly to develop an objective tool to help dermatologists detect melanoma at its earliest, most curable stages. Although melanoma is virtually 100% curable if detected at its earliest stage, one American dies from the disease every hour. We firmly believe that MelaFind has the potential to lower those tragic numbers. We are extremely pleased with the FDA's decision and will work diligently to answer all open questions and finalize the post-market study protocol in the coming weeks."

The Approvable Letter from the FDA comes on the heels of the CE Mark for MelaFind issued earlier this month. CE Mark approval allows MelaFind to be sold across the 27 nations of the European Union.

"MelaFind has the potential to provide dermatologists with significantly more information about indeterminate pigmented skin lesions to help us when deciding on which lesions to biopsy to detect melanoma as early as possible," said Darrell S. Rigel, MD, Clinical Professor of Dermatology at New York University Medical School. "While there have been incremental improvements in imaging tools for melanoma detection, we still primarily rely on our judgment based on a visual examination to select the lesions to biopsy; data show that this is often not enough."

"Taken together, the multiple clinical trials demonstrate that MelaFind represents a significant advance and should have a positive impact on patient outcomes once it's approved and available to dermatologists," said Laura K. Ferris, MD, PhD, Assistant

Professor of Dermatology and Director of the University of Pittsburgh Department of Dermatology Clinical Trials Unit.

The studies used to support the PMA application for MelaFind were the 1,383 patient U.S. pivotal trial and the companion reader study of 110 dermatologists: the device demonstrated a 98% sensitivity in the pivotal trial, whereas dermatologists had a 72% sensitivity in the adjunctive reader study.

MelaFind® Indications for Use

The FDA and MELA Sciences have agreed to the following labeled indications for use of MelaFind in the U.S.:

MelaFind is intended for use on clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma. MelaFind is designed to be used when a dermatologist chooses to obtain additional information for a decision to biopsy. MelaFind should NOT be used to confirm a clinical diagnosis of melanoma.

MelaFind is only for use by physicians trained in the clinical diagnosis and management of skin cancer (i.e., dermatologists) who have also successfully completed a training program in the appropriate use of MelaFind.

The MelaFind result is one element of the overall clinical assessment. MelaFind positive lesions (which may include malignant melanoma, melanoma *in situ*, high grade dysplastic nevi and atypical melanocytic proliferation/hyperplasia) should be considered for biopsy; the biopsy decision of a MelaFind negative lesion should be based on the remainder of the entire clinical context. Lesions that are “non-evaluable” by MelaFind should be carefully re-evaluated for biopsy.

MelaFind is indicated only for use on lesions with a diameter between 2 mm and 22 mm, lesions that are accessible by the MelaFind imager, lesions that are sufficiently pigmented (i.e. not for use on non-pigmented or skin-colored lesions), lesions that do not contain a scar or fibrosis consistent with previous trauma, lesions where the skin is intact (i.e., non-ulcerated or non-bleeding lesions), lesions greater than 1 cm away from the eye, lesions which do not contain foreign matter, and lesions not on special anatomic sites (i.e., not for use on acral, palmar, plantar, mucosal, or subungual areas). MelaFind is not designed to detect pigmented non-melanoma skin cancers, so the dermatologist should rely on clinical experience to diagnose such lesions.

Conference Call Information

MELA Sciences will host a conference call on Monday, September 26 at 8:30 am ET. To participate, please dial 888-204-4317 fifteen minutes before the conference is scheduled to begin. Callers outside of the U.S. should dial +816-581-1703. The conference call passcode is “MELA Sciences.” A live webcast of this call will be available in the investor

relations section of www.melasciences.com. A webcast replay of the call will be available for two weeks on the company's website by dialing 888-203-1112. Callers outside of the U.S. should dial +719-457-0820. The replay participant code is 8744426.

About Melanoma

Melanoma is the deadliest form of skin cancer, responsible for approximately 75% of skin cancer fatalities. The American Cancer Society estimates that there will be 70,230 new cases of invasive melanoma and about 8,790 related melanoma deaths in 2011 alone. The incidence of melanoma is on the rise. A 2008 National Cancer Institute report indicates that the annual incidence of melanoma among young adult Caucasian women rose 50% between 1980 and 2004.

The five year survival rate for patients with stage IV melanoma is less than 15%, with most patients dying within 6 to 10 months. Detecting early melanoma and conducting prompt treatment is essential to improving the prognosis. With early detection, surgical removal alone is usually the only required treatment because the melanoma is limited to the epidermis, the outer layer of skin. In this early stage, the cure rate with surgical removal is virtually 100%.

About MELA Sciences, Inc.

MELA Sciences is a medical device company focused on the design, development and commercialization of non-invasive tools to provide additional information to dermatologists during melanoma skin examinations. The company's flagship product, MelaFind®, is intended to be used when a trained dermatologist chooses to obtain additional information to help decide whether to biopsy certain indeterminate pigmented skin lesions. MelaFind has received the CE Mark and is approved for use in the European Union. The company has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) and is working to submit finalized labeling and other items to the agency to obtain marketing approval in the U.S.

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 company is able to sufficiently satisfy the requirements set forth in the FDA’s Approvable Letter or even if the company is able to sufficiently satisfy the requirements set forth in the FDA’s Approvable Letter whether MelaFind® ever achieves market acceptance or becomes commercially viable. 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.

For further information contact:

For Investors:
David Carey
Lazar Partners, Ltd.
646-871-8485

For Media
Melissa Hurley
Ricochet Public Relations
212-679-3300 x128