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): November 2, 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 November 2, 2011, MELA Sciences, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has approved the Company's pre-market approval application for MelaFind®. 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 November 2, 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: November 2, 2011

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

MELA Sciences Announces FDA Approval for MelaFind®

MelaFind represents one of the most significant advances in melanoma detection since the advent of the ABCD criteria established 25 years ago

Melanoma is the deadliest form of skin cancer, responsible for approximately 75% of skin cancer fatalities

Conference call scheduled for 10:00 a.m. ET

IRVINGTON, NY (November 2, 2011) — MELA Sciences (NASDAQ: MELA) today announced that the U.S. Food and Drug Administration (FDA) has approved the pre-market approval (PMA) application for MelaFind®.

“MelaFind is a groundbreaking technology and represents one of the most significant advances in early melanoma detection since the advent of the ABCD criteria that our group developed over a quarter century ago,” 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 eyes, experience and judgment. MelaFind provides objective information about indeterminate pigmented skin lesions to help us when deciding which lesions to biopsy to detect melanoma as early as possible when it can still be cured.”

“Melanoma is the deadliest form of skin cancer and rates of the disease are on the rise, especially in younger women,” said Susan Weinkle, MD, Assistant Clinical Professor of Dermatology, University of South Florida, President-elect of the American Society of Dermatologic Surgery, and Past President of the Women’s Dermatologic Society. “Early detection is our only chance for survival, and MelaFind has the potential to have a deep impact on this disease.”

Melanoma accounts for approximately 75% of skin cancer fatalities. Although melanoma is virtually 100% curable if detected at its earliest stage, one American dies from the disease every hour. Detection of early melanoma and conducting prompt treatment is essential to improving patient prognoses.

“The FDA approval of MelaFind marks the most important achievement in the company’s history and represents a significant advance for the millions of Americans who are at risk of developing this terrible disease,” said Joseph V. Gulfo, MD, President

and CEO, MELA Sciences. “We are actively working to prepare to launch MelaFind in the Northeast U.S. and Germany during the first quarter. We’re planning a steadfast, deliberate and measured approach to the commercial launch to ensure that dermatologists in practices of all shapes and sizes are trained and set up to use MelaFind effectively on the patients who can benefit most from the objective information that the system provides during skin examinations.”

In September, the company received CE Mark approval in the European Union, as well. Concurrent with its 2012 Northeastern U.S. rollout, the company plans to undertake a similar rollout strategy in Germany.

“We are thrilled that our years of persistence through the development and regulatory process have paid off,” Dr. Gulfo continued. “We are ready to start this new phase in the company’s history with the same energy, passion and tireless dedication that was responsible for this tremendous and rewarding accomplishment.”

The company submitted its PMA application to the FDA in June 2009. The studies used to support the PMA application for MelaFind were the 1,383-patient U.S. pivotal trial and the pivotal trial’s companion reader study of 110 dermatologists. The device demonstrated a 98% sensitivity in the pivotal trial, and a similar sensitivity in the reader study compared to a 72% sensitivity for participating dermatologists.

MelaFind systems will be placed initially in select, “high” volume, integrated dermatology and skin cancer specialists’ practices.

Based upon receipt of its FDA approval, the company withdrew its Citizen Petition filed with the FDA in May 2011 that focused on numerous irregularities in the PMA process, and requested that the FDA Commissioner enforce the binding protocol agreement between MELA Sciences and the FDA.

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 Wednesday, November 2, 2011 at 10:00 a.m. ET. To participate, please dial 888-806-6231 15 minutes before the conference is scheduled to begin. Callers outside of the U.S. should dial +913-312-0698. 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 or by dialing 888-203-1112. Callers outside of the U.S. should dial +719-457-0820. The replay participant code is 4163857.

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 six to 10 months. Detecting early melanoma and conducting prompt treatment is essential to improving the prognosis. With detection of early melanoma, 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. The FDA has approved MelaFind for use in the U.S. It has received the CE Mark for use in the European Union.

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 Melafind® 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.

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