



**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 18, 2010**

**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.)

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))
- 
-

## **TABLE OF CONTENTS**

[Item 8.01 — Other Events](#)

[Item 9.01 — Financial Statements and Exhibits](#)

[SIGNATURES](#)

[EXHIBIT INDEX](#)

[EX-99.1](#)

---

## [Table of Contents](#)

### **Item 8.01 — Other Events**

On November 18, 2010, MELA Sciences, Inc. (the “Company”) issued a press release announcing the results of the U.S. Food and Drug Administration’s (“FDA”) General and Plastic Surgery Devices Panel meeting in connection with the FDA’s review of the Company’s pre-market approval application for MelaFind®. The text of this press release is attached as Exhibit 99.1 and is incorporated herein by reference.

### **Item 9.01 — Financial Statements and Exhibits**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	MELA Sciences, Inc. Press Release, dated November 18, 2010

---

**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: November 18, 2010

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

---

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
99.1	MELA Sciences, Inc. Press Release, dated November 18, 2010



**MELA Sciences Announces FDA Advisory Panel Votes Positively  
for MelaFind® on Safety, Efficacy and Risk/Benefit Ratio**

***Decision Based on Data from Largest Prospective Study Ever Conducted in Melanoma Detection***

***- Company to Host Conference call November 19 at 7:30am ET -***

**COLLEGE PARK, MD — (November 18, 2010)** — MELA Sciences, Inc. (NASDAQ: MELA) today announced that the General and Plastic Surgery Devices Panel appointed by the U.S. Food and Drug Administration (FDA) voted by majority that, for its proposed indications, MelaFind® is safe and effective and that its benefits outweigh the risks.

“We are extremely pleased with the results of today’s panel vote and look forward to working with the FDA during its ongoing review of the MelaFind PMA application,” said Joseph V. Gulfo, MD, President and CEO of MELA Sciences. “Melanoma is virtually 100% curable if detected at its earliest stage. The unfortunate reality is that one person in the U.S. dies from the disease every hour and it’s the number one cancer killer in women ages 30-35. We designed MelaFind to provide clinicians with objective information that can aid their decision on whether or not to biopsy a pigmented skin lesion that has characteristics of melanoma at its earliest stage.”

“I believe that MelaFind can be a valuable tool to provide input into the decision to biopsy suspicious skin lesions and may ultimately help save lives,” said Darrell Rigel, MD, Clinical Professor of Dermatology at New York University Medical School.

“I believe that this will also help dermatologists who evaluate pigmented skin lesions under the microscope to be more accurate in diagnosis,” said Clay J. Cockerell, MD, Clinical Professor of Dermatology & Pathology, University of Texas southwest Medical Center, Dallas, TX.

The FDA will take into account, among other things, the panel’s recommendation in making its final approval decision. The FDA has not provided a date as to when it will make a decision regarding the MelaFind® PMA application.

**Conference Call and Webcast**

MELA Sciences will host a conference call on Friday, November 19 at 7:30 am ET. To participate, please dial 866-783-2139 fifteen minutes before the conference is scheduled to begin. Callers outside of the U.S. should dial +857-350-1598. 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](http://www.melasciences.com). A webcast replay of the call will be

---

available for two weeks on the company's website or by dialing 888-286-8010. Callers outside of the US should dial +617-801-6888. The replay participant code is 45603438.

### **About MELA Sciences**

MELA Sciences is a medical technology company focused on developing MelaFind®. MelaFind® is a non-invasive and objective multi-spectral computer vision system designed to aid physicians in the detection of early melanoma from among clinically atypical (those having one or more clinical or historical characteristics of melanoma, such as asymmetry, border irregularity, color variegation, diameter greater than 6 millimeters, evolving, patient concern, regression, and ugly duckling) cutaneous pigmented lesions that are non-ulcerated, not bleeding, and less than 2.2 centimeters in diameter, when a physician chooses to obtain additional information before making a final decision to biopsy to rule out melanoma.

The MelaFind® Pre-Market Approval (PMA) application was filed with the U.S. Food and Drug Administration (FDA) in June 2009 and is currently under review at the FDA. 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](http://www.melasciences.com).

### **About Melanoma**

Melanoma is the deadliest form of skin cancer, responsible for approximately 75% of skin cancer fatalities. The melanoma rate has continued to increase with an estimated 120,000 new cases projected in 2010. A recent National Cancer Institute report published in the July 10, 2008 online edition of the Journal of Investigative Dermatology indicates that annual incidence of melanoma among young adult Caucasian women rose 50% between 1980 and 2004. Melanoma is the most common cancer in women age 25 to 29 and the number one cancer killer of women age 30 to 35. Although no cure is currently available for advanced-stage melanoma, if caught early, melanoma is virtually 100% curable.

### **Safe Harbor**

This press release includes "forward-looking statements" within the meaning of the Private 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 "may," "will," "should," "estimates," "expects," "contemplates," "anticipates," "plans," "intends," "believes" 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 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 economic, business, competitive, market and regulatory factors. We base our forward-looking statements on information currently available to us, and we assume no obligation to update them.

For further information contact:

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

For Media:  
Hollister Hovey  
Lazar Partners, Ltd.  
646-871-8485