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): March 10, 2016



STRATA SKIN SCIENCES, INC. (Exact Name of Registrant Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation) 000-51481 (Commission File Number) **13-3986004** (I.R.S. Employer Identification No.)

100 Lakeside Drive, Suite 100, Horsham, Pennsylvania (Address of Principal Executive Offices)

(Zip Code)

19044

Registrant's telephone number, including area code: 215-619-3200

N/A

(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:

□ 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))

Item 8.01 Other Events.

On March 10, 2016 the Company announced that the FDA has determined a recent PMA supplement to include additional information in the MelaFind® system output as approvable. This step means that the MelaFind output will now include classifier score data, quantitative information derived by the MelaFind system, in addition to the previously approved binary result.

In connection with this event, the Company issued a press release, a copy of which is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit No. Exhibit Description

99.1 Press Release dated March 10, 2016

SIGNATURE

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.

By:

STRATA SKIN SCIENCES, INC. /s/ Michael R. Stewart

Michael R. Stewart President and Chief Executive Officer

Date: March 10, 2016

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STRATA Skin Sciences, Inc. Announces FDA Approval of PMA Supplemental for MelaFind®

Study including Classifier Score Data shows increased Sensitivity and Specificity

FDA Post-Approval Study Termination provides cost savings

Greater flexibility to explore strategic value of MelaFind System in Clinical Dermatology

Horsham, PA - March 10, 2016 - STRATA Skin Sciences, Inc. ("STRATA"), (NASDAQ: SSKN), a medical technology company dedicated to developing and commercializing innovative products for the treatment and diagnosis of serious dermatological disorders, announced today that the U.S. Food and Drug Administration (FDA) approved STRATA's PMA supplement for the MelaFind System.

MelaFind is a non-invasive, point-of-care instrument to aid in the detection of melanoma. The FDA approved MelaFind's use of the "classifier score data", a quantitative result derived by the MelaFind System that can be beneficially used in conjunction with the previously approved binary result (yes/no) from the instrument. With the Classifier Score, Dermatologists will be in possession of more complete information when utilizing MelaFind to aid in their decision to biopsy an ambiguous skin lesion.

To provide evidence to support the supplement, STRATA developed a reader study protocol in conjunction with the FDA and conducted a live study at the Fall Clinical Dermatology Conference that took place on October 1, 2015. This study measured the impact of the MelaFind binary result plus classifier score information on a dermatologist's decision to biopsy suspicious pigmented skin lesions. A total of 160 Board Certified dermatologists participated.

The results of the study showed average sensitivity (ability to detect disease) increased from 76% before the utilization of MelaFind to 92% following the use of MelaFind. Average specificity (ability to rule out disease) increased from 52% before to 79% after MelaFind utilization. These statistically significant results satisfied the requirements for approval of the PMA Supplement. The full results of the study are being prepared for submission to a peer-reviewed publication.

In conjunction with the acceptance of these study results by the FDA, the Agency agreed that STRATA could terminate the previously required Post Approval Study for MelaFind ("PAS") that had been underway since 2012 and was expected to continue for several additional years.

Michael R. Stewart, STRATA's president and CEO commented: "We appreciate the FDA working with us to achieve approval of MelaFind's classifier score labelling information that better assists dermatologists in the use of the MelaFind device and reaching agreement to terminate the post approval study. The study we conducted demonstrates the value of the MelaFind device in the hands of a dermatologist. Moreover, the opportunity to terminate the PAS eliminates future costs of millions of dollars to the Company that would have been associated with the continuation of the PAS."

"The supplement approval gives us the flexibility to evaluate the potential for broader acceptance of the MelaFind device in the market as we continue to examine ways to create enhanced value for STRATA from this technology," continued Mr. Stewart. "The Company's primary focus near term remains on the growth of the XTRAC[®] system recurring revenues for the treatment of psoriasis and vitiligo. While the MelaFind is not expected to contribute materially to STRATA's 2016 revenues, the receipt of the PMA supplement approval regarding the classifier score, and the associated meaningful results of the Reader study are positive steps in our strategic assessment of the MelaFind technology."

About STRATA Skin Sciences, Inc. (Formerly MELA Sciences, Inc.)

(www.strataskinsciences.com)

STRATA Skin Sciences is a medical technology company focused on the therapeutic and diagnostic dermatology market. Its products include the XTRAC[®] laser and VTRAC[®] excimer lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions, and the MelaFind[®] system used to assist in the identification and management of melanoma skin cancer.

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 the Company's plans, objectives, expectations and intentions and may contain words such as "will," "may," "seeks," and "expects," that suggest future events or trends. These statements, including the Company's ability to generate the anticipated revenue stream, the Company's ability to generate sufficient cash flow to fund the Company's ongoing operations beginning at any time in the future, and the Company's ability to build a leading franchise in medical dermatology, including the ability of the Company to advance and market the MelaFind technology, are based on the Company's current expectations and are inherently subject to significant uncertainties and changes in circumstances. Actual results may differ materially from the Company's 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 set forth in the Company's SEC reports on Forms 10-Q and 10-K. Given such uncertainties, any or all of these forward-looking statements may prove to be incorrect or unreliable. The Company assumes no duty to update its forwardlooking statements and urges investors to carefully review its SEC disclosures available at www.sec.gov and www.strataskinsciences.com.

Investor Contacts: Christina L. Allgeier, CFO STRATA Skin Sciences, Inc. 215-619-3267

callgeier@strataskin.com

Bob Yedid LifeSci Advisors, LLC 646-597-6989 Bob@LifeSciAdvisors.com