
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): August 2, 2018

STRATA
SKIN SCIENCES

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 19044
(Address of Principal Executive Offices) (Zip Code)

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

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure

On August 6, 2018 the Company announced that on August 2, 2018 the U.S. Food and Drug Administration ("FDA") had granted a 510(k) clearance to the Company for its Multi-Micro Dose™ ("MMD") tip accessory for its proprietary XTRAC® 308nm excimer laser. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

Safe Harbor Statement

Statements in this report that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, the Company's continuing efforts to implement changes to our business with the goal of enhancing our strategic position in the medical and aesthetic dermatology market; ability to achieve growth in recurring revenues and other business sectors, ability to achieve and sustain a successful direct to customer marketing strategy and execution of that strategy, and the Company's ability to commercialize the MMD device are based on the Company's current expectations and are inherently subject to significant uncertainties and changes in circumstances. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any results expressed or implied by such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement. The Company is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this report as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits

(d)	<u>Exhibits</u>
99.1	Strata Skin Sciences Press Release Dated August 6, 2018

Exhibit No.
99.1

Exhibit Description
August 6, 2018 STRATA Skin Sciences, Inc. Press Release

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.

STRATA SKIN SCIENCES, INC.

Date: August 6, 2018

By: /s/ Matthew C. Hill
Matthew C. Hill
Chief Financial Officer

STRATA Skin Sciences Announces FDA Granted 510(k) Clearance for the Multi Micro Dose™ Tip for its XTRAC® 308nm Excimer Laser

MMD Tip Offers Faster Patient Outcomes at Uncompromised Safety, Higher Patient Retention and Lower Costs for Patient and Payer

Horsham, PA, August 6, 2018 — STRATA Skin Sciences (NASDAQ: SSKN) ("STRATA"), a medical technology company in Dermatology and Plastic Surgery dedicated to developing, commercializing, and marketing innovative products for the treatment of dermatologic conditions, today announced that the U.S. Food and Drug Administration ("FDA") has granted a 510(k) clearance to the Company for its Multi-Micro Dose™ ("MMD") tip accessory for its proprietary XTRAC® 308nm excimer laser.

The Multi-Micro Dose Tip accessory is indicated for use in conjunction with the XTRAC laser system to filter the Narrow Band -UVB ("NB-UVB") light at delivery in order to calculate and individualize the maximum non-blistering dose for a particular patient.

The patent-pending MMD Tip simultaneously applies multiple level doses of energy to a specific area of the patient's psoriatic plaque, thereby identifying the maximum sub-blistering energy dose for a particular treatment zone. Utilizing the results from these test patches, the physician can design the optimal therapeutic dose treatment for each patient. The optimization of the dose levels should result in a shorter treatment regimen to achieve clearance.

The XTRAC® excimer laser delivers a highly targeted therapeutic beam of NB-UVB light and is cleared by the FDA to treat psoriasis, vitiligo, eczema, atopic dermatitis and leukoderma – skin diseases which impact over 35 million patients in the United States alone. This technology is covered by multiple patents, including exclusive rights patents for the delivery of treatments to Vitiligo patients.

Dr. Dolev Rafaeli, STRATA's Chief Executive Officer, stated, "This is an exciting and important step for the Company and an amazing achievement after years of development. We believe that the MMD is a significant step on the path to developing the Optimal Therapeutic Dose protocol, which is intended to provide faster patient outcomes and higher patient satisfaction, and we expect that it will result in increased patient retention for our partner clinics. Initial clinical data shown in previously issued peer reviewed studies is promising and we look forward to providing the results of our MMD pilot clinical study by the fourth quarter of this year. We anticipate that the study will validate the achievement of clinical end points with a lower number of treatments."

Large insurance providers already guide physicians to consider NB-UVB treatment, such as the one offered by XTRAC, as a first line of treatment, requiring a failure to respond prior to approving and covering treatments with targeted immune modulators (Biologics treatment).

Current physician protocol with NB-UVB can extend over an 8-to-10 week period. STRATA views the OTD protocol, which has shown patients reaching PASI-75 in as short as two weekly

treatments using the MMD diagnostics tool, as a breakthrough to shortened treatment times; offering faster, no side-effect resolution for patients, lower cost for payers, and enhanced business for our partner clinics that enjoy the XTRAC Direct-to-Consumer patient awareness advertisement campaign.

About STRATA Skin Sciences, Inc. (www.strataskin.com)

STRATA Skin Sciences is a medical technology company in Dermatology and Plastic Surgery dedicated to developing, commercializing and marketing innovative products for the treatment of dermatologic conditions. Its products include the XTRAC® excimer laser and VTRAC® lamp systems utilized in the treatment of psoriasis, vitiligo and various other skin conditions; and the STRATAPEN® MicroSystem, marketed specifically for the intended use of micropigmentation.

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 and research and development activities beginning at any time in the future, the public's reaction to the Company's new advertisements and marketing campaigns under development, and the Company's ability to build a leading franchise in dermatology and aesthetics, the Company's ability to grow revenues and sustain that growth, the Company's ability to influence physician practice to utilize the OTD device for shorter patient treatment protocols, and the uncertainty of the outcomes of clinical studies, 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 10K filed with the SEC on March 30, 2018.

Investor Contacts:

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