
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): June 19, 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
(Address of Principal Executive Offices)

19044
(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 June 19, 2018 the Company issued a press release announcing that it had submitted an application to the Food and Drug Administration (FDA) for a 510(k) clearance for its Multi-Micro Dose™ ("MMD") tip accessory for the 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 secure 510(k) clearance for 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) Exhibits
99.1 Strata Skin Sciences Press Release Dated June 19, 2018

Exhibit No.
99.1

Exhibit Description
[June 19, 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: June 19, 2018

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

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

Horsham, PA, June 19, 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 submission of its 510(k) application to the Food and Drug Administration (FDA) for its Multi-Micro Dose™ ("MMD") tip accessory for the proprietary XTRAC® 308nm excimer laser.

"This is an important milestone for the Company and is the first step in our plan to introduce the Optimal Therapeutic Dose™ treatment protocol, to provide faster patient outcomes, higher patient satisfaction, and to drive more patients to our partner clinics," said Dr. Dolev Rafaeli, Chief Executive Officer of STRATA. "With its ability to apply simultaneous doses of energy to the psoriatic plaque, the MMD tip, when cleared, will allow physicians to optimize treatments more quickly. We look forward to introducing the MMD Tip upon FDA clearance."

The patent pending MMD Tip applies multiple high-energy doses at varying levels of energy to the patient's psoriatic plaque. Data have shown that higher doses of the XTRAC treatment achieved PASI-75 clearance in as little as two to four weekly treatments, as compared to an average of 6.2 treatments in previously published studies.

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. Nothing in this press release is intended to indicate that the FDA has cleared the MMD device for marketing or that the sought after indications for use will be allowed by the FDA.

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

STRATA's unique business model leverages targeted Direct to Consumer (DTC) advertising to generate awareness and utilizes its in-house call center and insurance advocacy teams to increase volume for the Company's partner dermatology clinics.

The XTRAC® business has used this proven DTC model to grow its domestic dermatology partner network to over 740 clinics, with a worldwide installed base of over 2,000 devices. The Company is able to offer 90% of DTC patients an introduction to physicians prescribing a

reimbursable solution, using XTRAC®, within a 10-mile radius of their house. The Company is a leader in dermatology in-clinic business generation for its partners.

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, and the Company's ability to secure FDA 510k clearance for the OTD device 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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