

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 15, 2021

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.)

5 Walnut Grove Drive, Suite 140, Horsham, 19044
Pennsylvania
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	SSKN	The NASDAQ Stock Market LLC

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 March 15, 2021, STRATA Skin Sciences, Inc. (the “Company”) issued a press release announcing that an independent study was published in the Journal of The European Academy of Dermatology and Venereology on the treatment of Vitiligo using the Company’s XTRAC excimer laser.

The information set forth under this Item 7.01, including Exhibit 99.1 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 such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following press release is furnished as an exhibit to this Current Report on Form 8-K pursuant to Item 7.01 and shall not be deemed to be “filed”:

99.1 Press Release dated March 15, 2021 issued by STRATA Skin Sciences, Inc.

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: March 15, 2021

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

STRATA Skin Sciences Announces Independent Study Published in the Journal of The European Academy of Dermatology and Venereology

Vitiligo Repigmentation Achieved in Five Treatments with XTRAC® Excimer Laser

HORSHAM, Pa. March 15, 2021 — (NASDAQ: SSKN) STRATA Skin Sciences, Inc. (“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 the publication of an independent study on the treatment of vitiligo using the Company’s XTRAC excimer laser. The study was conducted by a team of dermatologists in Japan and was approved by the Ethics Committee of Kansai Medical University Kori Hospital. The results of the study were published in the November 2020 issue of the *Journal of The European Academy of Dermatology and Venereology*.

The study results demonstrated that patients with refractory vitiligo achieved satisfactory repigmentation in five treatments, including those who were previously unresponsive to conventional treatments such as topical steroids, excimer light and narrowband UVB light. These patients were treated under a minimal blistering dose protocol using the XTRAC excimer laser, which provided better therapeutic effects with fewer treatments as compared to other UVB phototherapies. The study attributed better patient outcomes to XTRAC’s higher irradiation rate as compared to other available UVB phototherapies. In addition, the XTRAC treatments were well tolerated, and the use of a minimal blistering dose was shown to potentially reduce the number of treatment sessions required, thereby lessening the burden on patients and medical staff.

“We are delighted to see independent studies performed that continue to validate and highlight the efficacy of our XTRAC excimer laser in treating dermatologic diseases,” said Bob Moccia, President and Chief Executive Officer. “There is a large unmet need in Japan for the treatment of vitiligo, a devastating condition with limited treatment options. As we continue our focus on delivering our therapy solution to patients in Japan, we are encouraged by the positive results of this study to support our efforts; the data clearly demonstrate improved clinical outcomes with XTRAC treatments over the alternatives to treat vitiligo.”

Reference - Noborio, R., Nomura, Y., Nakamura, M., Nishida, E., Kiyohara, T., Tanizaki, H. and Morita, A. (2021), Efficacy of 308-nm excimer laser treatment for refractory vitiligo: a case series of treatment based on the minimal blistering dose. J Eur Acad Dermatol Venereol.

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.

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 31 million patients in the United States alone. The technology is covered by multiple patents, including exclusive rights for patents for the delivery of treatment 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 832 clinics, with a worldwide installed base of over 2,300 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.

The Company has now introduced its Home by XTRAC™ business, leveraging in-house resources; including DTC advertising, in-house call center and its insurance reimbursement team to provide an at-home, insurance-reimbursed treatment option for patients with certain skin diseases that do not qualify for in-office treatments.

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, the Company’s ability to generate the growth in its core business, the Company’s ability to develop social media marketing campaigns, and the Company’s ability to build a leading franchise in dermatology and aesthetics, the Company’s ability to develop a business for home-based treatment of skin diseases, 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, adverse market conditions or supply chain interruptions resulting from the corona virus and political factors or conditions affecting the Company and the medical device industry in general, future responses to and effects of COVID-19 pandemic, 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 these forward-looking statements may prove to be incorrect or unreliable. The statements in this press release are made as of the date of this press release, even if subsequently made available by the Company on its website or otherwise. The Company does not undertake any obligation to update or revise these statements to reflect events or circumstances occurring after the date of this press release. The Company urges investors to carefully review its SEC disclosures available at www.sec.gov and www.strataskin.com.

Investor Contacts:

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