## 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): April 6, 2020



### STRATA SKIN SCIENCES, INC.

(Exact Name of Registrant Specified in Charter)

**Delaware**(State or Other
Jurisdiction of Incorporation)

**000-51481** (Commission File Number)

(I.R.S. Employer Identification No.)

13-3986004

5 Walnut Grove Drive, Suite 140, 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))

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

	Trading	
Title of each class	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 wheth	her the registrant is an emerging	g growth company as	defined in Rule	405 of the Securities	Act of
1933 (§230.405 of this chapter	r) or Rule 12b-2 of the Securitie	s Exchange Act of 193	4 (§240.12b-2 of	f this chapter).	

Emerging growth company  $\Box$ 

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.  $\Box$ 

### **Item 7.01 Regulation FD Disclosure**

On April 6, 2020, Strata Skin Sciences (the "Company") issued a press release announcing the peer-reviewed publication of a clinical study report entitled: "*Treatment of Plaque Psoriasis with an Excimer Laser Utilizing an Optimal Therapeutic UVB Dose Protocol*" in the April, 2020 issue of the Journal of Drugs in Dermatology.

The article summarizes the results of the authors' findings of a multi-center clinical study on the efficiency and efficacy of the Company's Optimal Therapeutic Dose Therapy utilizing the Multi-Micro Dose® diagnostic tip for STRATA's proprietary XTRAC® 308nm excimer laser in the treatment of plaque psoriasis, using the Optimal Therapeutic Dose (OTD).

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.

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

Exhibits.

Exhibit Number Description

99.1 STRATA Skin Sciences Press Release dated April 6, 2020

#### **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: April 6, 2020

By: <u>/s/ Matthew C. Hill</u>

Matthew C. Hill

Chief Financial Officer

## STRATA Skin Sciences, Inc. Announces Study Published in the Journal of Drugs in Dermatology

92% of participants achieved reduction in mPASI score of 75% or more after receiving Optimal Therapeutic Dose Therapy with the Multi-Micro Dose® diagnostic tip for the treatment of their plaque psoriasis

**Horsham, PA, April 6, 2020** — STRATA Skin Sciences, Inc. (NASDAQ: SSKN) ("STRATA" or the "Company"), 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 peer-reviewed publication of a clinical study report entitled: "*Treatment of Plaque Psoriasis with an Excimer Laser Utilizing an Optimal Therapeutic UVB Dose Protocol*" in the April, 2020 issue of the Journal of Drugs in Dermatology.

The article, authored by Quinn Thibodeaux, MD, Kristen Beck, MD, Benjamin N. Lockshin, MD, Neal Bhatia, MD, Ethan Levin, MD, John Koo, MD, and Tina Bhutani, MD, summarizes the results of a multi-center clinical study investigating the efficiency and efficacy of the Multi-Micro Dose® diagnostic tip accessory for STRATA's proprietary XTRAC® 308nm excimer laser in treatment of plaque psoriasis. Centers that participated in the study include: Department of Dermatology, Psoriasis & Skin Treatment Center, University of California (San Francisco), Clinical Trials Center at DermAssociates, U.S. Dermatology Partners, Clinical Dermatology and Therapeutics Clinical Research.

## Results from the study demonstrated:

- · 92% of the participants responded to treatment and achieved a reduction in mPASI score of 75% or more
- A statistically significant improvement in mPASI score by the **second** treatment and an mPASI reduction of 50% or more after an average of **four** sessions, compared to the current average of 16 to 20 treatments with NB-UVB 308 nm devices
- · Results were durable, with patients maintaining a reduction in their mPASI scores of 50% or more for 60 days
- Further, statistical analysis predicts mPASI scores to stay below 50% of baseline for 78 days
- The clinical study is available online at https://jddonline.com/articles/dermatology/S1545961620P0349X/1

Dr. Dolev Rafaeli, the Company's President and CEO stated, "The data was impressive with faster reduction in mPASI and 92% of patients exceeding the endpoint of overall reduction after receiving Optimal Therapeutic Dose Protocol, utilizing the Multi-Micro Dose diagnostic tip. Publication of this study in the Journal of Drugs in Dermatology, a well-respected peer-reviewed journal, is a tremendous validation of our new OTD protocol and its ability to provide faster, more convenient patient outcomes, greater patient satisfaction and lower costs for payers and patients alike."

Commenting on the implications of COVID-19 on XTRAC procedures, Dr. Rafaeli added, "The XTRAC excimer laser is a safe and effective treatment with no systemic side effects on a patient's immune system. Additionally, due to serious concerns from the impact of COVID-19 in immune compromised patients, we are anticipating that more physicians will choose XTRAC for their new patients and will likely switch some of their existing patients treated with systemic immunosuppressants to the XTRAC treatment. The American Academy of Dermatology has recently published guidelines for providers to follow for patients on biologic therapy during this Coronavirus Pandemic: guidance document on the use of biological agents during the COVID-19 outbreak."

## **About STRATA Skin Sciences, Inc.** (www.strataskinsciences.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 <sup>®</sup> excimer laser and VTRAC <sup>®</sup> 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 35 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 820 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, and oral statements made regarding the subjects of this release contains "forward-looking statements" within the meaning of the Securities Litigation Reform Act of 1995, or the Reform Act, which may include, but are not limited to, statements regarding the Company's revenue growth estimates, plans, objectives, expectations and intentions and other statements contained in this press release that are not historical facts, including statements identified by words such as "believe," "plan," "seek," "expect," "intend," "estimate," "anticipate," "will," and similar expressions. All statements addressing 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; litigation and regulatory proceedings to which the Company might be subject; the Company's ability to implement business strategies, including its acquisition, business development and comeback strategies; the Company's acquisition and business development strategy may not be successful in locating advantageous targets; the Company's ability to successfully integrate any assets, liabilities, customers, systems and management personnel it acquires into its operations and its ability to realize related revenue synergies, strategic gains and cost savings may be significantly harder to achieve, if at all, or may take longer to achieve; potential goodwill impairment charges, future impairment charges and fluctuations in the fair values of reporting units or of assets in the event projected financial results are not achieved within expected time frames; the Company's debt and debt service requirements which may restrict its operational and financial flexibility, as well as imposing unfavorable interest and financing costs; the Company's ability to maintain its existing credit facilities or obtain satisfactory new credit facilities; regulatory and political factors or conditions affecting the Company and/or the medical device industry in general; the public's reaction to the Company's advertisements and marketing campaigns, and the Company's ability to build a leading franchise in dermatology and aesthetics, the impact of COVID-19 on the use of XTRAC or COVID-19's impact on the dermatological segment, and the Company's ability to grow revenues and sustain that growth as well as statements expressing optimism or pessimism about future operating results are forward-looking statements within the meaning of the Reform Act. The forward-looking statements are based on management's current views and assumptions regarding future events and operating performance, and are inherently subject to significant business, economic, and competitive uncertainties and contingencies and changes in circumstances, many of which are beyond the Company's control. 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.

Although the Company does not make forward-looking statements unless it believes it has a reasonable basis for doing so, the Company cannot guarantee their accuracy. The foregoing factors, among others, could cause actual results to differ materially from those described in these forward-looking statements. For a list of other factors which could affect the Company's results, including revenue growth estimates, see the Company's filings with the Securities and Exchange Commission, including "Cautionary Note Regarding Forward-Looking Statements," "Item 1A. Risk Factors," and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" set forth in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019. No undue reliance should be placed on any forward-looking statements.

#### **Investor Contacts:**

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