

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): October 1, 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, 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))

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 October 1, 2018 the Company issued a press release announcing the completion of a multi-center clinical study investigation on the efficiency and efficacy of its FDA cleared Multi-Micro Dose™ ("MMD") diagnostic tip accessory for the proprietary XTRAC® 308nm excimer laser. As well as identifying the first commercial account to utilize the MMD. 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. 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 October 1, 2018

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	<a href="#">October 1, 2018 STRATA Skin Sciences, Inc. Press Release</a>

**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: October 1, 2018

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

## **STRATA Skin Sciences Announces Completion of a Clinical Study and the First Commercial Account for its Multi Micro Dose™ Diagnostic Tip Accessory for the XTRAC® 308nm Excimer Laser**

**Horsham, PA, October 1, 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 the completion of a multi-center clinical study investigating the efficiency and efficacy of its FDA cleared Multi-Micro Dose™ ("MMD") diagnostic tip accessory for the proprietary XTRAC® 308nm excimer laser.

Three separate clinics utilized the patent-pending MMD tip, in conjunction with the XTRAC laser, to filter the narrow band UVB light at delivery in order to calculate and customize the maximum non-blistering dose for each of the participating patients in the study.

The MMD tip simultaneously applies multiple level doses of energy to a specific area of a 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. This proprietary process was trademarked by STRATA as the Optimal Therapeutic Dose (OTD) and is intended to provide faster patient outcomes and greater patient satisfaction. The clinical study was designed to measure increased efficacy and determine the minimum number of treatment sessions necessary to achieve desired clinical endpoints.

Following the OTD process, the physician determines the maximum non-blistering dose for 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, shown in previously published studies at lower doses.

The statistical analysis of the clinical study results, based on the XTRAC treatment protocol which utilized the Optimal Therapeutic Dose (OTD), revealed the following findings:

- 92% of the included participants responded to treatment by achieving a reduction in mPASI score of 75% or more
  - As compared to the current average of 16-20 treatments conducted with NB-UVB 308nm devices, the treatment produced statistically significant mPASI improvement by the **second** treatment. It took an average of **four** sessions for patients to reduce mPASI by 50% or more relative to baseline
  - Patients were followed post treatment and have maintained reduction in mPASI score of 50% or more for 60 days
-

- Further, statistical survival models predict mPASI scores to stay below 50% of baseline for 78 days

The company anticipates the full clinical study report to be submitted for publication.

Dr. Ben Lockshin, former Chair of the Research Committee and on the Board of Directors for the National Psoriasis Foundation (NPF) and a principal investigator on this study, stated, "I am pleased to see how quickly my patients can achieve meaningful improvement in just a few treatments. I believe this will greatly increase patient satisfaction."

Dr. Lockshin, has engaged with the company to become the first commercial site providing OTD XTRAC treatments using the MMD tip, and further commented, "I believe integrating the OTD approach will allow me to provide the safe and effective treatment that reduces the time commitment and cost for my patients while achieving the clinical results we have come to expect with XTRAC."

Dr. Dolev Rafaeli, STRATA's Chief Executive Officer noted "Introducing the Optimal Therapeutic Dose™ treatment protocol and making it commercially available is a very important milestone for STRATA and its partner clinics. This new protocol will provide faster patient outcomes, greater patient satisfaction, lower costs for payers and patients alike, and increased patient traffic to our partner clinics. This dynamic combination of MMD's proprietary technology and the OTD protocol is exclusively available to our physician partners, differentiating their clinical delivery and adding to the technological superiority of the XTRAC platform as compared with all other available treatment modalities. We look forward to the expansion of the commercial use of the MMD diagnostic tip across our partner network of over 1,000 providers."

**About STRATA Skin Sciences, Inc.** ([www.strataskin.com](http://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:**

Matthew Hill, Chief Financial Officer  
STRATA Skin Sciences, Inc.  
215-619-3200  
ir@strataskin.com

Jeremy Feffer, Managing Director  
LifeSci Advisors, LLC  
212-915-2568  
jeremy@lifesciadvisors.com