

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): November 2, 2020

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, 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:

| 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 November 2, 2020, Strata Skin Sciences (the "Company") issued a press release announcing the peer-reviewed publication of a clinical study report entitled: "*Therapies for Psoriasis: Clinical and Economic Comparisons*" in the November, 2020 issue of the Journal of Drugs in Dermatology.

The study compared common interventions to treat plaque psoriasis and found the XTRAC excimer laser and its Optimal Therapeutic Dose (OTD™) treatment protocol utilizing the Multi Micro Dose™ (MMD®) diagnostic tip delivered the fastest results with the fewest adverse events at the most economical cost of all treatments analyzed.

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 November 2, 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: November 2, 2020

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

STRATA Skin Sciences' XTRAC® Technology Found to Be Most Effective and Most Economical Treatment for Plaque Psoriasis Compared to Other Therapies

*Delivers fastest results with fewest adverse events compared to topical, traditional UV, biologic and systemic therapies
Providing a better solution for Integrated Health Systems and Capitation healthcare – managing the patients and reducing costs
for chronic skin disease
Up to 97% savings over Biologic drugs*

Horsham, PA, November 2, 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 publication of a peer-reviewed health-economic study entitled: "Therapies for Psoriasis: Clinical and Economic Comparisons" in the November 2020 issue of the Journal of Drugs in Dermatology. The study was conducted by Dr. Albert Marchetti, a leading health economic researcher and an adjunct professor at Rutgers New Jersey Medical School, and compared common interventions to treat plaque psoriasis. The Company's XTRAC excimer laser and its Optimal Therapeutic Dose (OTD™) treatment protocol utilizing the Multi Micro Dose™ (MMD®) diagnostic tip were found to deliver the fastest results with the fewest adverse events at the most economical cost of all treatments analyzed, including topical, traditional UV, biologic and systemic therapies. In addition, patients treated with the XTRAC excimer laser and XTRAC with MMD had fewer actual treatment days compared to all other modalities and was the only therapy where patients achieved remission without a maintenance therapy.

“This study was an extraordinarily comprehensive analysis of all treatment methodologies, so it is very gratifying to note that our XTRAC excimer laser and XTRAC with MMD devices were determined to be the best of all approaches, producing clinical outcomes comparable to the most effective biologics, at a fraction of the cost. This health economic assessment is very timely in light of the COVID19 pandemic, as psoriasis patients and providers now have increased concern over the use of biologics. The clinical and cost data from the study can help practitioners select appropriate treatments for patients currently using a biologic therapy and those with comorbidities,” said Dr. Dolev Rafaeli, STRATA's President and Chief Executive Officer. “With over 600 integrated health systems, managing over 100 million patients, annually, the ability to offer a cost effective solution makes XTRAC the perfect alternative to other more expensive treatment options like Biologic drugs,” concluded Dr. Rafaeli.

The XTRAC system is used in multiple Integrated Health System clinics; including Mt. Sinai, Kaiser Permanente and The United States Department of Veterans Affairs, in addition to its prevalent use by private practice physicians.

The study analyzed four main psoriasis therapeutic modalities; including topicals, systemics, phototherapy, and biologics. Researchers selected eight comparators (Methotrexate for systemics, Clobetasol (CLO) and Calcipotriene (CAL) combination for topicals and Etanercept (ETA), Infliximab (INF), and Ustekinumab (UST) for biologics, narrow-band UVB (NB-UVB), XTRAC with and without MMD technology (Optimal Therapeutic Dose OTD Protocol (published in the April 2020 issue of Journal of Drugs in Dermatology) for phototherapy) that were preferentially used within each category, widely studied, and supported by high-quality published research and data to represent each of the four modalities. Each therapy was analyzed for required care days, likelihood of response, speed and completeness of response, frequency and duration of remission, adverse events and their management, resource utilization, and cost.

Dr. Marchetti noted, “We were impressed by the effectiveness of the XTRAC technology and that it showed significant savings compared to other therapies. The study conclusions highlight the superiority of the XTRAC technology for treatment of psoriasis patients as being the least expensive, fastest onset, having the fewest adverse events, and having the ability to achieve remission without the need of maintenance therapy.”

The study was overseen by an advisory board comprised of Dr. Tina Bhutani, MD, MAS (Assistant Clinical Professor, Department of Dermatology, Co-Director, Psoriasis & Skin Treatment Center, University of California San Francisco, CA); Dr. Ben Lockshin, MD FAAD (Director, Clinical Trials Center at U.S. Dermatology Partners, Silver Spring, MD; Assistant Professor, Georgetown University); and Dr. Frederick Behringer, MD (Private Practitioner, Suncoast Skin Solutions, Ocala, FL).

Results of the research show:

- Clinical Effectiveness – XTRAC produces excellent clinical outcomes with superior PASI 75 reduction in a high percentage (92% for XTRAC OTD) of patients.
- Speed of Response to Treatment – XTRAC excimer laser and the XTRAC MMD diagnostic tip achieve visible results within 5-7 weeks as compared to systemics and biologics that require 3 months.
- Adverse Events – Treatment with XTRAC technology is shown to be the safest of all modalities for plaque psoriasis. Adverse events are mild, temporary, localized, and well tolerated.
- Cost-Effectiveness of the XTRAC Technology – Among patients with moderate-to-severe psoriasis, the XTRAC excimer laser and XTRAC MMD diagnostic tip produce clinical outcomes (an end point of PASI 75) that are comparable to biologics at just 3% of the cost.
- Time Spent by Patients in Treatment - Actual treatment days per year for the XTRAC excimer laser used in conjunction with the MMD accessory (18) and XTRAC (39) are significantly less than most other modalities: Etanercept (70 days), Methotrexate (62 days), NB-UVB (80 days) and, topicals (294 days), resulting in higher convenience and significantly lower patient frustration.
- Remission Without Maintenance Therapy – XTRAC is the only treatment modality where patients can achieve 2.5 - 6 months of disease remission without the need of a maintenance therapy, providing more enjoyable treatment free days.

The full study can be accessed on page 1101 (89 of 124 on the following link): [Journal of Drugs in Dermatology](#).

About STRATA Skin Sciences, Inc.

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 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 789 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, the Company's ability to generate the growth in its core business, develop and grow an international recurring business model, the Company's ability to develop social media marketing campaigns, and the Company's ability to build a leading franchise in dermatology and aesthetics, 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, 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:

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