

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): January 23, 2020



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 January 23, 2020 the Company announced the new U.S. Food and Drug Administration (FDA) 510(k) clearance for the Company's XTRAC Momentum Excimer Laser System, Model AL10000 platform. The XTRAC excimer laser incorporates new features including increased power range, short-hair scalp tip and on-board database.

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 January 23, 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: January 23, 2020

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

STRATA Skin Sciences, Inc. Receives A 510(k) Clearance For Its XTRAC Momentum 308nm Excimer Laser Platform

New features include increased power range, short-hair scalp tip and on-board database to improve patient safety, treatment efficiency and ease-of-use

Horsham, PA, January 23, 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 new U.S. Food and Drug Administration (FDA) 510(k) clearance for the Company’s XTRAC Momentum Excimer Laser System, Model AL10000 platform (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193478>).

The XTRAC excimer laser delivers a highly targeted therapeutic beam of UVB light and is cleared to treat psoriasis, vitiligo, eczema, atopic dermatitis and leukoderma – skin diseases that impact over 35 million patients in the United States alone. The different platforms (Ultra, Velocity and now Momentum) offer clinical providers functionality and usability to support the thousands of domestic and international devices.

The new clearance is the first full platform clearance (since the XTRAC Velocity platform was cleared in 2010). Named Momentum, the cleared platform creates the foundation for the upcoming technological developments in the Company’s worldwide install base.

The additional features cleared as part of the Momentum platform include:

- An increased power range helping to improve patient safety and treatment efficiency, allowing for higher patient volumes
- A new and exclusive proprietary short-hair tip, improving ease of use in difficult-to-treat scalp psoriasis
- An enhanced interface and database, improving functionality and capacity to manage patient information

“We are proud to receive clearance of the full XTRAC Momentum platform. Our R&D team is continually working to improve our systems and devices, and we are now beginning to see the fruits of that labor with our second 510(k) clearance in the last two years and first full XTRAC platform clearance since 2010.” said Dr. Dolev Rafaeli, the Company’s President and CEO. “Strata and its XTRAC Excimer laser platforms dominate the dermatology global marketplace, further distancing Strata from other Excimer platforms that have not improved their specifications in over 12 years. We look forward to additional advances and clearances as our team continues to expand the capabilities of this technology platform.”

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 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 new advertisements and marketing campaigns under development, and the Company's ability to build a leading franchise in dermatology and aesthetics, 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, 2018. No undue reliance should be placed on any forward-looking statements.

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