
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): September 5, 2017

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, Pennsylvania
(Address of Principal Executive Offices)

19044
(Zip Code)

Registrant's telephone number, including area code: 215-619-3200

N/A
(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 8.01. Other Events.

On September 5, 2017, we received a response letter from the U.S. Food and Drug Administration (the "FDA") concerning possible paths for 510k clearance of our new Optimal Dosing Technology ("OTD") proposed to be used for the treatment of psoriasis, vitiligo and other skin conditions.

The FDA response letter proposes two alternative paths for seeking regulatory clearance. The first path requires a clinical trial to substantiate potential claims for the OTD, and the second path is to seek regulatory clearance with no new claims regarding treatment or efficacy. Should the Company take the second path, we will likely consider initiatives to develop potential proprietary features for the OTD technology. The Company is assessing the alternatives for proceeding and is considering related costs and the availability of cash resources. The Company's ability to finance either path or a combination of them and other product development would be enhanced from the additional cash resources that would result from the proposed conversion of its outstanding convertible debentures due in 2021, including the interest savings of approximately \$4.0 million over the next four years.

Cautionary Statement Regarding Forward-Looking Statements

This Form 8-K 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 possible paths for obtaining 510k clearance from the FDA of our new ODT and financing such development, 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 SEC reports on Forms 10-Q and 10-K. Given such uncertainties, any or all of these forward-looking statements may prove to be incorrect or unreliable. The Company assumes no duty to update its forward-looking statements and urges investors to carefully review its SEC disclosures available at www.sec.gov and www.strataskin.com.

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.

By: /s/ Christina Allgeier

Christina Allgeier
Chief Financial Officer

Date September 6, 2017