

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): July 17, 2024

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
(Address of Principal Executive Offices)

19044
(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.

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

Item 7.01. Regulation FD Disclosure.

On July 17, 2024, STRATA Skin Sciences, Inc. (the “Company”) issued a press release announcing the publication of a clinical study titled, “Advancing precision acne therapy using a photopneumatic device,” in the July 11, 2024 issue of the *Journal of Cosmetic and Laser Therapy*.

In the study, the Company’s TheraClear®X Acne Therapy System was shown to reduce lesions and associated skin redness with improvement in skin texture and pore size after one to three treatments with infrequent adverse effects, providing benefit as monotherapy and/or as an adjuvant. The ability to change pulse structure, pulse duration, vacuum pressure, and fluence (i.e., energy intensity) allowed for treatment that best matched skin type and acne therapy.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act or otherwise subject to the liabilities of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following press release is furnished as an exhibit to this Current Report on Form 8-K and shall not be deemed to be “filed”:

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press release dated July 17, 2024, issued by Strata Skin Sciences, Inc.

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: July 17, 2024

By: /s/ Christopher Lesovitz
Christopher Lesovitz
Chief Financial Officer

STRATA Skin Sciences' TheraClear®X Acne Therapy System Found Safe and Effective in Study Published in Peer Reviewed Journal

Study published in Journal of Cosmetic and Laser Therapy highlights the TheraClear®X photopneumatic device as an effective treatment option, either as monotherapy or in combination with topical or oral treatments, for patients with mild-moderate acne

HORSHAM, Penn., July 17, 2024 – STRATA Skin Sciences, Inc. (“STRATA” or the “Company”) (NASDAQ: SSKN), a medical technology company dedicated to developing, commercializing, and marketing innovative products for the treatment of dermatologic conditions, announces the publication of a clinical study titled, “Advancing precision acne therapy using a photopneumatic device,” in the July 11, 2024 issue of the *Journal of Cosmetic and Laser Therapy*.

In the study, the TheraClear®X Acne Therapy System was shown to reduce lesions and associated skin redness with improvement in skin texture and pore size after one to three treatments with infrequent adverse effects, providing benefit as monotherapy and/or as an adjuvant. The ability to change pulse structure, pulse duration, vacuum pressure, and fluence (i.e., energy intensity) allowed for treatment that best matched skin type and acne therapy.

The study sought to evaluate visible improvements in acne lesions and skin texture after a series of tailored photopneumatic therapy applications delivered to patients with mild-moderate acne. Seven female patients with inflammatory, comedonal, and pustular lesions were evaluated after up to six treatments, one to two weeks apart for 15-20 minutes per treatment using customized energy settings. The results demonstrate:

- All patients experienced a visible reduction in comedones, pustules, and inflammatory acne lesions and achieved $\geq 50\%$ clearance after three treatments
- Patients also experienced overall improvements in skin texture with reduction in redness, pore size, oiliness, perilesional erythema, and acne-induced hyperpigmentation
- Side effects experienced by patients were mild and transient and included mild erythema, mild bruising, superficial erosions, and temporary pigmentation changes (48–72 hours post-treatment)
- All patients stated that TheraClear®X treatment was "comfortable"

The study was conducted by Gilly Munavalli, MD, MHS, FACMS, the medical director and founder of Dermatology, Laser, & Vein Specialists of the Carolinas in Charlotte, North Carolina and Assistant Clinical Professor of Dermatology at the Wake Forest University Department of Dermatology. Dr. Munavalli has been in private practice for 20 years and has over 100 scientific publications and book chapters and has served as principal investigator in a broad range of clinical research trials and 10 FDA pivotal trials.

“I am very satisfied with the study results. The study shows TheraClear®X as a monotherapy is well tolerated and delivers visible improvements in facial acne lesions and skin texture,” commented Dr. Munavalli. “Tailored vacuum and energy settings based on individual acne severity allow for precision therapy, aligning with skin type and personalized acne care recommendations. This tailored, non-drug, physician-administered intervention offers a promising alternative for acne patients resistant to traditional therapies, overcoming compliance challenges associated with topical and oral treatments.”

STRATA’s TheraClear®X is a photopneumatic device that is FDA-cleared as a noninvasive, in-office treatment for mild-to-moderate acne, including comedonal, pustular, and inflammatory acne vulgaris. TheraClear®X combines gentle vacuum with pulsed broadband light to treat acne. The vacuum pulls dermal structures toward the skin surface and withdraws the contents of the follicles. Broadband light activates porphyrins to destroy Cutibacterium acnes and reduce sebum production. The vacuum is released when the process is completed. The treatment is administered through a handheld delivery system that is liquid-cooled for patient comfort and has no patient downtime. Treatment requires no pre-medication or anesthesia.

“The results of this study are consistent with known clinical use of the TheraClear®X device and other published studies that demonstrate the benefits of photopneumatic therapy in the treatment of mild to moderate acne,” said STRATA’s President and CEO Dr. Dolev Rafaeli. “Acne affects tens of millions of people on the U.S. alone each year and can prove difficult to treat from topical or oral treatment alone. Photopneumatic therapy is emerging as a viable treatment modality, and it is gratifying to see proven results in a growing number of investigator-initiated studies.”

The full study can be accessed with the following link:

<https://doi.org/10.1080/14764172.2024.2376704>

About STRATA Skin Sciences

STRATA Skin Sciences is a medical technology company dedicated to developing, commercializing, and marketing innovative products for the in-office treatment of various dermatologic conditions, such as psoriasis, vitiligo, and acne. Its products include the XTRAC® excimer laser, VTRAC® lamp systems, and the TheraClear®X Acne Therapy System.

STRATA is proud to offer these exciting technologies in the U.S. through its unique Partnership Program. STRATA’s popular partnership approach includes a fee per treatment cost structure (versus an equipment purchase), installation and use of the device, on-site training for practice personnel, service and maintenance of the equipment, dedicated account and customer service associates, and co-op advertising support to help raise awareness and promote the program within the practice.

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 launch and sell products recently acquired or to be developed in the future, the Company's ability to develop social media marketing campaigns, direct to consumer 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 labor supply shortages, or supply chain interruptions resulting from fiscal, political factors, international conflicts, responses, or conditions affecting the Company, the medical device industry and our customers and patients 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 Contact:

CORE IR
516-222-2560
IR@strataskin.com