

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): August 26, 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 August 26, 2024, STRATA Skin Sciences, Inc. (the “Company”) issued a press release announcing that it has filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania against LaserOptek America Corp. (“LaserOptek”), Monarch Aesthetic Services, Inc. d/b/a Monarch Laser Services (“MLS”), and The Pinnacle Health Group (“Pinnacle”), collectively referred to as the “Defendants” citing unfair competition under federal and state laws regarding the marketing and sales of competitive laser devices.

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 August 26, 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: August 26, 2024

By: /s/ Dolev Rafaeli
Dr. Dolev Rafaeli
Chief Executive Officer

STRATA Skin Sciences Files Complaint Against LaserOptek, Monarch Laser Services, and The Pinnacle Health Group

HORSHAM, Penn., August 26, 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, has filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania against LaserOptek America Corp. (“LaserOptek”), Monarch Aesthetic Services, Inc. d/b/a Monarch Laser Services (“MLS”), and The Pinnacle Health Group (“Pinnacle”), collectively referred to as the “Defendants” citing unfair competition under federal and state laws regarding the marketing and sales of competitive laser devices.

LaserOptek, a Korean company publicly traded on the KOSDAQ exchange, is the manufacturer of the Pallas line of solid-state laser medical devices (“Pallas lasers”), MLS is the exclusive distributor of the Pallas lasers in the U.S., and Pinnacle was engaged by LaserOptek to provide advisory services regarding marketing of the Pallas lasers and reimbursement of psoriasis treatment procedures performed with Pallas lasers.

In its complaint, STRATA alleges false advertising and unfair competition under the Lanham Act and related state laws with regard to the marketing and sale of the Pallas lasers in the U.S. by the Defendants. Specifically, STRATA claims that:

- The Defendants have intentionally misrepresented the nature, characteristics, and qualities of the *solid-state Pallas lasers* by falsely stating to current and potential dermatology practice customers that treatments for psoriasis performed with Pallas lasers are reimbursable using specific medical codes reserved only for psoriasis treatments performed with *excimer lasers*, such as STRATA’s XTRAC® devices
- LaserOptek and MLS have also made knowingly false and misleading statements regarding the technological, functional, and clinical equivalence and/or superiority of the solid-state Pallas lasers over STRATA’s excimer lasers without any scientific or technical evidence to support those claims
- LaserOptek and MLS have relied on LaserOptek’s clearance from the Food and Drug Administration (FDA) to make inherently misleading and false statements regarding the technological, functional, or clinical equivalence of the solid-state Pallas lasers as compared to STRATA’s excimer lasers
- The Defendants’ conduct is causing ongoing harm to the public interest by encouraging the fraudulent use of reimbursement codes, causing purchasers and users of the Pallas lasers to experience probable denials of insurance reimbursement, and causing patients to be treated for psoriasis using Pallas lasers that have not been determined to have clinical efficacy by the Centers for Medicare and Medicaid Services (CMS) and the American Academy of Dermatology (AAD) and for which clinical efficacy has not been established in the peer-reviewed scientific literature

STRATA is seeking injunctive relief, actual damages, treble damages, disgorgement of profits, and reimbursement of legal costs from the Defendants.

“STRATA will protect the ethical billing and use of CMS reimbursable treatment codes for the benefit of our 4,000 partners providing dermatology treatments using our proven excimer devices and the hundreds of thousands of patients in the U.S. that have enjoyed the benefit of psoriasis treatment from our devices that offer a cheaper and faster treatment option with minimal side effects,” commented STRATA’s President and CEO Dr. Dolev Rafaeli. “Additionally, we have observed LaserOptek’s efforts to sell its Pallas lasers to dermatology practices in international markets, only to see such customers convert back to our XTRAC® devices after finding the Pallas lasers to be unstable and lacking in efficacy.”

About STRATA Skin Sciences, Inc.

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.

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