

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 11, 2024



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 November 11, 2024, STRATA Skin Sciences, Inc. (the “Company” or “STRATA”) issued a press release announcing that the United States District Court for the Eastern District of Pennsylvania entered a court order in favor of the Company in its complaint 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. Among other things, the court order bars LaserOptek and other parties acting at its direction from engaging in any sales, advertising, marketing or promotion of Pallas lasers that states or implies, directly or indirectly, that treatments with Pallas laser systems are reimbursable using CPT Codes 96920-96922, and further enjoins those parties from engaging in any sales, advertising, marketing or promotion of Pallas lasers in the United States that includes any false or misleading statements regarding the Pallas lasers or STRATA’s lasers.

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>
<a href="#">99.1</a>	Press release dated November 11, 2024, issued by Strata Skin Sciences, Inc.

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**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 12, 2024

By: Dolev Rafaeli  
Dr. Dolev Rafaeli  
Chief Executive Officer

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**STRATA Skin Sciences Announces Favorable Court Order in Complaint Against LaserOptek, Monarch Laser Services, and The Pinnacle Health Group**

**HORSHAM, Penn., November 11, 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 that the United States District Court for the Eastern District of Pennsylvania entered a court order in favor of the Company in its complaint 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.”

On August 19, 2024, STRATA filed a Complaint and a Motion for a Preliminary Injunction against the Defendants, citing unfair competition under federal and state laws regarding the marketing and sales of LaserOptek’s Pallas lasers in the United States. On November 8, 2024, the United States District Court for the Eastern District of Pennsylvania entered a court order pursuant to which:

- *LaserOptek and The Pinnacle Health Group, their employees, agents, sales representatives, distributors, officers, directors, and all those acting at their direction are enjoined from engaging in any sales, advertising, marketing or promotion of Pallas lasers that states or implies, directly or indirectly, that treatments with Pallas laser systems are reimbursable using CPT Codes 96920-96922; and*
- *LaserOptek and The Pinnacle Health Group, their employees, agents, sales representatives, distributors, officers, directors, and all those acting at their direction are further barred from engaging in any sales, advertising, marketing or promotion of Pallas lasers in the United States that includes any false or misleading statements regarding the Pallas lasers or STRATA’s lasers*

The court order was issued following a joint stipulation by the parties and as a partial conclusion of STRATA’s motion for a preliminary injunction. STRATA will continue pursuing its claims for equitable and monetary relief from LaserOptek and other parties acting in concert with them.

STRATA President and CEO Dr. Dolev Rafaeli commented, "We are satisfied with this partial resolution of our preliminary injunction demands, as it saves both parties time and resources. We look forward to the outcome of the litigation, as we intend to vigorously defend users, patients and our own partner clinics from the damaging use of a non-excimer laser that seeks reimbursement under the CPT codes established over 20 years ago and re-affirmed for exclusive use of treatments with excimer lasers by the American Medical Association CPT board. The attempt by distributors and sellers of technologies that are neither clinically proven nor comparable to our XTRAC® excimer laser technology to mislead current and potential users, while making false technological and efficacy claims, puts providers at risk of an unethical use of the CPT codes. To protect the integrity of our products, intellectual property, and brand, as well as our clinical partners and the underlying healthcare system, we are compelled to take legal action in instances like this. In addition to the potential harm to patients and providers, it is STRATA's opinion that the monetary and reputational damages incurred by STRATA from the defendants' behavior is significant and continues to mount, and we will continue to pursue this legal course of action to address this."

LaserOptek, a Korean company publicly traded on the KOSDAQ exchange, is the manufacturer of the Pallas line of solid-state laser medical devices, 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.

#### **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](http://www.sec.gov) and [www.strataskin.com](http://www.strataskin.com).

#### **Investor Contact:**

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