

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 6, 2026

Vivani Medical, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36747
(Commission
File Number)

02-0692322
(IRS Employer
Identification No.)

1350 S. Loop Road
Alameda, California
(Address of principal executive offices)

94502
(Zip Code)

Registrant's telephone number, including area code: (415) 506-8462

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))

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, par value \$0.0001 per share	VANI	The Nasdaq Capital Market

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.

Vivani Medical, Inc. issued a press release titled "Vivani Medical Announces Successful Dosing of All Participants in SLIM-1, a Phase 1 Trial Evaluating NPM-139, a Miniature, Ultra Long-Acting Semaglutide Implant for Chronic Weight Management." The press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information contained in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities under that Section. Furthermore, the information contained in this Item 7.01 and Exhibit 99.1 shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated August 6, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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.

VIVANI MEDICAL, INC.

Date: August 6, 2026

By: /s/ Donald Dwyer
Name: Donald Dwyer
Title: Chief Business Officer

Vivani Medical Announces Successful Dosing of All Participants in SLIM-1, a Phase 1 Trial Evaluating NPM-139, a Miniature, Ultra Long-Acting Semaglutide Implant for Chronic Weight Management

Dosing of the first participant commenced ahead of schedule and was rapidly followed by initial dosing in all trial participants.

SLIM-1™ trial is a Phase 1, randomized, controlled clinical trial design to characterize the safety, tolerability, and pharmacokinetics of NPM-139 including a Wegovy® (semaglutide injection) group.

Top-line data from the 20-participant trial is expected in November of 2026.

ALAMEDA, Calif., August 6, 2026 (GLOBE NEWSWIRE) – Vivani Medical, Inc. (Nasdaq: VANI) today announced full enrollment and successful initial dosing of all participants in its SLIM-1™ Phase 1 trial for NPM-139, a miniature, subdermal semaglutide implant being designed to provide six- to twelve-months of continuous drug delivery utilizing our proprietary NanoPortal™ technology. The trial of 20 GLP-1 naïve participants in Australia includes low-doses of NPM-139 and Wegovy® to assess safety, tolerability, and pharmacokinetics. Changes in weight will be measured.

“Dosing of the first 10 participants occurred on July 29, ahead of schedule. The remaining 10 participants were dosed one week later. All insertion procedures were completed successfully without any issues. Expedient full enrollment of SLIM-1 trial participants highlights our commitment to rapidly advance the development of our innovative GLP-1 product candidates in chronic weight management and type 2 diabetes,” said Adam Mendelsohn, Ph.D., CEO of Vivani Medical. “We look forward to sharing top-line SLIM-1 clinical data later this year which we anticipate will pave the way for initiation of a Phase 2 dose-ranging trial in 2027.”

This milestone follows NPM-139 preclinical studies demonstrating sustainable 20% weight reduction in animal models and a July 2026 agreement with Novo Nordisk to evaluate NPM-139 and Vivani’s proprietary NanoPortal implant technology.

In addition to NPM-139’s primary aim to improve convenience, medication adherence and tolerability, NanoPortal implants are uniquely designed to enable infrequent administration (six months or longer) and the ability to rapidly reverse GLP-1 drug exposure when cessation of therapy is needed or desired. Reversibility can be an important clinical consideration in certain situations, including when a woman becomes pregnant or when patients undergoing surgery have an increased aspiration risk.

About SLIM-1

SLIM-1 is an open-label, active-controlled trial evaluating a low-dose NPM-139 (semaglutide implant) given to 10 participants, and the starting dose of Wegovy (0.25mg/week semaglutide injection) also given to 10 participants, over a four-week duration. The trial is designed to evaluate the safety, tolerability and pharmacokinetic profile in overweight or obese participants who are otherwise healthy. Top-line results from SLIM-1 are expected to be available in November.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani develops miniature, biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence and improving patient tolerance to their medication. Vivani is developing a portfolio of GLP-1 based implants for metabolic diseases including obesity and type 2 diabetes. These NanoPortal implants are designed for once- or twice-yearly administration to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the numerous challenges associated with the daily or weekly administration of orals and injectables, including tolerability issues and loss of efficacy. Medication non-adherence occurs when patients do not take their medication as prescribed. This affects an alarming number of patients, approximately 50%, including those taking daily pills. For more information, please visit: www.vivani.com.

Forward-Looking Statements

This press release contains certain “forward-looking statements” within the meaning of the “safe harbor” provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: “target,” “believe,” “expect,” “will,” “may,” “anticipate,” “estimate,” “would,” “positioned,” “future,” and other similar expressions that are used in this press release, including statements regarding Vivani’s business, products in development, including the therapeutic potential thereof, the planned development thereof, and its technology, strategy, cash position and financial runway. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on Vivani’s current beliefs, expectations, and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of Vivani’s control. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, risks of unexpected costs or delays, and risks and uncertainties associated with the development and commercialization of products and product candidates that may impact or alter anticipated business plans, strategies and objectives. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Vivani’s expectations in any forward-looking statement. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties are more fully described in periodic filings with the U.S. Securities and Exchange Commission (the “SEC”) including the factors described in Vivani’s most recent Quarterly Report on Form 10-Q filed with the SEC on May 13, 2026, as updated by future filings with the SEC. Any forward-looking statement made by Vivani in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of added information, future developments or otherwise, except as required by law.

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