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): March 26, 2025

Vivani Medical, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36747**	**02-0692322**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1350 S. Loop Road
Alameda, California 94502
(Address of principal executive offices, including zip code)

(415) 506-8462
(Telephone number, including area code, of agent for service)

(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 8.01 Other Events.

On March 26, 2025, Vivani Medical, Inc. (the "Company") announced pre-clinical data for NPM-139, the Company's subdermal semaglutide implant under development for chronic weight management in obese and overweight individuals. A copy of the press release issued in connection with this announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Vivani Medical, Inc. on March 26, 2025.
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 thereunto duly authorized.

VIVANI MEDICAL, INC.

Date: March 26, 2025

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

Exhibit 99.1

Vivani Medical Announces Positive Preclinical Weight Loss Data for NPM-139 Semaglutide Implant, with Potential for Once-Yearly Dosing

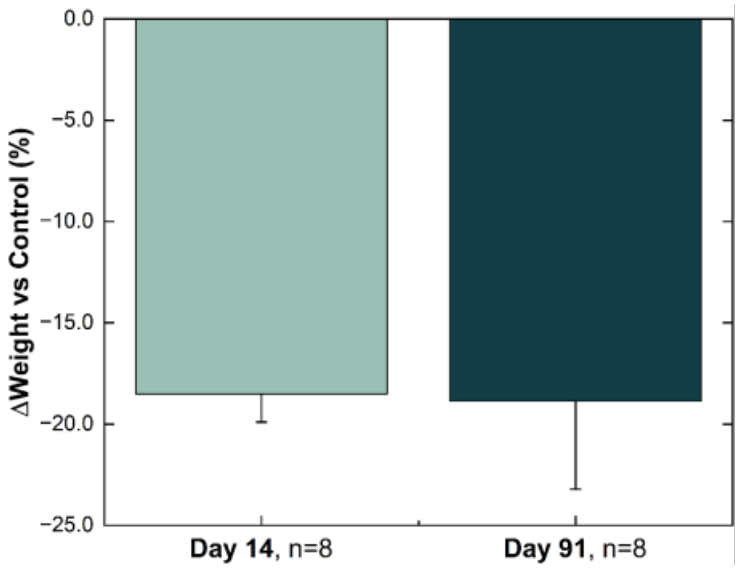
NanoPortal™ technology successfully delivers semaglutide, the active ingredient in Ozempic®/Wegovy®, in a preclinical study with NPM-139 (semaglutide implant)

NPM-139 treatment resulted in nearly 20% placebo-adjusted weight loss from a single administration with expected once or twice-yearly dosing

NPM-139 is a miniature, subdermal implant in development for chronic weight management designed to guarantee medication adherence and potentially improve treatment tolerability by providing smooth and steady delivery of GLP-1 therapy

ALAMEDA, Calif., March 26, 2025 -- (Globe Newswire) -- Vivani Medical, Inc. (NASDAQ: VANI) ("Vivani" or the "Company"), a clinical-stage biopharmaceutical company developing miniature, ultra long-acting drug implants, today announced promising preclinical data for NPM-139, its subdermal semaglutide implant under development for chronic weight management in obese and overweight individuals. These results reinforce the company's commitment to addressing chronic weight management and other chronic diseases by leveraging its proprietary NanoPortal™ implant technology which is designed to enable smooth and steady delivery of therapeutic molecules including GLP-1 therapy. This development marks a significant advancement in improving medication adherence and patient convenience, addressing a critical gap in the treatment of chronic diseases including obesity and type 2 diabetes.

"Products containing semaglutide generated $25 billion in 2024 and demand for these products continues to soar. Since over half of these patients regularly miss doses as indicated by real-world medication adherence data, we believe that there is a tremendous opportunity for a more convenient delivery option that will eliminate missed doses and thereby improve real-world health outcomes. We continue to believe that the primary expected advantages of our proprietary NanoPortal implant technology, improving medication adherence and medication tolerability, have the potential to transform and expand the adoption of GLP-1 therapy in the future," said Adam Mendelsohn, Ph.D., Vivani Medical's Chief Executive Officer. "This preclinical demonstration of NPM-139 comes on the heels of having rapidly enrolled and successfully implanted an initial group of subjects in LIBERATE-1, our first-in-human study with NPM-115, which we expect will pave the road for NPM-139 as development continues for both programs."



Weight difference versus control group in healthy Sprague-Dawley Rats. % weight change from baseline for NPM-139 (semaglutide) corrected to control (sham implant). Values are mean ± SE.

In an ongoing study in healthy rats, a single administration of the semaglutide implant NPM-139 resulted in body weights that were nearly 20% lower than a sham implant control group throughout a 91-day treatment period. Like NPM-119 and NPM-115, NPM-139 has demonstrated smooth, non-fluctuating *in vivo* release; this was confirmed by pharmacokinetic data from this study which demonstrated continuous and steady semaglutide exposure throughout the study period. NPM-139 has previously demonstrated therapeutic semaglutide exposure levels in pharmacokinetic data over a six-month duration in healthy rats. *In vitro* chemical and physical stability measurements for durations exceeding one year indicate the potential for once-yearly administration of NPM-139. Together, these data demonstrate the versatility of the NanoPortal technology beyond NPM-115 (exenatide implant) and provide significant encouragement for continued development of each program.

The ongoing NPM-115 clinical study, LIBERATE-1, for which the first successful implantation was recently announced, remains on track to produce top-line data by mid-2025. While LIBERATE-1 will primarily inform continued development of NPM-115, LIBERATE-1 will also provide critical information to support the development of NPM-139 and other pipeline programs since it represents the first human application of the NanoPortal technology.

About LIBERATE-1

LIBERATE-1 is a Phase 1, first-in-human study of a miniature, ultra long-acting GLP-1 (exenatide) implant, NPM-115, to investigate the safety, tolerability, and full pharmacokinetic profile in obese or overweight subjects. The trial has enrolled participants who are intended to be titrated on weekly semaglutide injections for 8 weeks (0.25 mg/week for 4 weeks followed by 0.5 mg/week for 4 weeks) before being randomized to receive a single administration of Vivani's exenatide implant (NPM-115, n=8), weekly exenatide injections (Bydureon BCise®, n=8), or weekly 1 mg semaglutide injections (Wegovy®, n=8) for a 9-week treatment duration. Changes in weight will be measured. The study is currently on-going at two study centers in Australia and is fully enrolled. Top-line data from the study is anticipated to be available in mid-2025.

Vivani has successfully utilized research and development rebates from the Australian government for relevant 2024 expenses to defray a portion of the costs from this clinical trial and anticipates being able to utilize similar rebates going forward. Since clinical studies conducted in Australia comply with the International Conference on Harmonization guidelines, data generated in Australia generally are acceptable to the U.S. Food and Drug Administration and other regulatory authorities. Vivani anticipates use of relevant clinical data generated in Australia to support regulatory submissions in other geographies including the United States. Additional guidance regarding future regulatory submissions will be provided as new information becomes available.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani develops biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence, and potentially to improve patient tolerance to their medication. Vivani's lead program, NPM-115, is a six-month, subdermal, GLP-1 (exenatide) implant under development for chronic weight management in obese or overweight individuals. Vivani's emerging pipeline includes NPM-139 (semaglutide implant) which is also under development for chronic weight management. The semaglutide implant is being initially developed as a twice-yearly implant but it has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's six-month, subdermal, GLP-1 (exenatide) implant under development for the treatment of type 2 diabetes. These NanoPortal implants are designed to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the challenges associated with the daily or weekly administration of orals and injectables. 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. Medication non-adherence, which contributes to more than $500 billion in annual avoidable healthcare costs and 125,000 potentially preventable deaths annually in the U.S. alone, is a primary and daunting reason why obese or overweight patients, and patients taking type 2 diabetes or other chronic disease treatments, face significant challenges in achieving positive real-world effectiveness. While the current GLP-1 landscape includes over 50 new molecular entities under clinical stage development, Vivani remains confident that its highly differentiated portfolio of miniature long-acting GLP-1 implants have the potential to provide an attractive therapeutic option for patients, prescribers and payers. 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 US 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 in this press release, including statements regarding Vivani's business, products in development, including the therapeutic potential thereof, the planned development therefor, the completion of the LIBERATE-1 trial and reporting of trial results, Vivani's emerging development plans for NPM-115, NPM-139, NPM-119, or Vivani's plans with respect to its wholly owned subsidiary, Cortigent Inc., and Vivani's 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. 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. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, risks related to the development and commercialization of Vivani's products, including NPM-115, NPM-139, and NPM-119; delays and changes in the development of Vivani's products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct Vivani's development activities; risks related to the initiation, enrollment and conduct of Vivani's planned clinical trials and the results therefrom; Vivani's history of losses and Vivani's ability to access additional capital or otherwise fund Vivani's business; market conditions and the ability of Cortigent to complete its intended spin-off from the Company. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties can be found in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission filed on March 26, 2024, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. 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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