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 11, 2024

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	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 July 11, 2024, Vivani Medical, Inc. (the "Company") announced that the Company expects to initiate the first clinical study in the Company's NPM-115 program in the fourth quarter of 2024. The Company's NPM-115 clinical program will evaluate the investigational 6-month GLP-1 implant for the treatment of patients with obesity or overweight patients with a related comorbidity. 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 July 11, 2024.
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: July 11, 2024

By: /s/ Brigid A. Makes
Name: Brigid A. Makes
Title: Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Vivani Medical Provides Update on Clinical Development Plans for Miniature, Long-term, GLP-1 Obesity Implant Program, NPM-115

Vivani expects to initiate the first clinical study supporting the NPM-115 program in the fourth quarter of 2024

The NPM-115 clinical program will consist of a series of studies designed to support the development of Vivani's miniature, 6-month GLP-1 (exenatide) NanoPortal™ implant for chronic weight management in obese or overweight patients

ALAMEDA, Calif., July 11, 2024 -- (BUSINESS WIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), an innovative, biopharmaceutical company developing novel, long-term drug implants, today announced that it expects to initiate the first clinical study in the NPM-115 program in the fourth quarter of 2024 in Australia, pending regulatory clearance in that country. The NPM-115 clinical program will evaluate the investigational 6-month GLP-1 implant for chronic weight management in patients who are either obese or overweight with a related comorbidity.

"In February, our company announced that we were re-prioritizing the development of our GLP-1 implants to focus on the treatment of obesity and chronic weight management in response to the significant medical need and unprecedented market demand," said Adam Mendelsohn, Ph.D., Vivani's President and Chief Executive Officer. "Today we can report that our first-in-human study, LIBERATE-1, is expected to enroll patients who are obese or overweight to primarily support NPM-115's development program. We anticipate initiating this clinical study in Australia later this year."

Dr. Mendelsohn continued: "The results of LIBERATE-1 may support initiation of a subsequent clinical study, pending regulatory clearance, to explore higher and potentially more effective doses of our exenatide implant on weight and tolerability in obese or overweight patients. Once the target dose is identified, we intend to study an implant at that dose over the full 6-month duration, over which our implant has already demonstrated encouraging results in preclinical animal models. Additionally, we believe the results of LIBERATE-1 may provide clinical validation of our NanoPortal drug delivery technology to support a broader application of the technology in the treatment of chronic diseases."

LIBERATE-1 will be a randomized investigation of the safety, tolerability and pharmacokinetic profile of the exenatide NanoPortal implant in obese or overweight patients. The study will enroll patients who will be titrated on weekly semaglutide injections (Wegovy®) 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 (n=8), weekly exenatide injections Bydureon BCise® (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. The exenatide implant to be used in LIBERATE-1 is expected to produce comparable exenatide exposure levels as Bydureon BCise. Changes in weight will be measured. The trial is expected to initiate later this year with data projected to be available in 2025.

Background

On February 28, 2024, Vivani announced positive preclinical weight loss data from its exenatide implant in support of its NPM-115 development program which was comparable to semaglutide injections (the active pharmaceutical ingredient in Ozempic®/Wegovy®) and a strategic shift to prioritize its obesity portfolio.

On June 13, 2024, Vivani announced that the U.S. Food and Drug Administration ("FDA") cleared its Investigational New Drug for its exenatide implant to be studied in patients with type 2 diabetes in support of the NPM-119 development program. The Company previously announced an intention to initiate the first study in the NPM-119 program in the second half of this year. As a result of reprioritizing the focus of its GLP-1 implants on the treatment of obesity and chronic weight management, the Company plans to first pursue the NPM-115 study. Dr. Mendelsohn noted that the NPM-115 program utilizes the same exenatide implant as NPM-119, and the only difference is the population to be studied.

Vivani plans to submit an application to a Human Research Ethics Committee in Australia to support the initiation of the Company's first in human study supporting the NPM-115 program in that country. If available, Vivani intends to utilize research and development incentives and rebates from the Australian government in order to defray a portion of the costs from the trial. Since clinical studies conducted in Australia comply with the International Conference on Harmonization guidelines and data generated in Australia are acceptable to the FDA and other regulatory authorities, Vivani anticipates use of relevant clinical data generated in Australia to support regulatory submissions in other geographies including the US. Additional guidance will be provided as new information becomes available.

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 our business, products in development, including the therapeutic potential thereof, the planned development therefor, the initiation of the LIBERATE-1 trial and reporting of trial results, our emerging development plans for NPM-115 and NPM-119 clinical programs. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our 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 our 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 our products, including those produced from the NPM-115 and NPM-119 clinical programs; delays and changes in the development of our products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct our development activities, including our ability to obtain regulatory clearance to conduct LIBERATE-1 in Australia, commence clinical development; risks related to the initiation, enrollment and conduct of our planned clinical trials and the results therefrom; our history of losses and our ability to access additional capital or otherwise fund our business; market conditions and the ability of Cortigent to complete its initial public offering. 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 Exchange Commission filed on March 26, 2024, as updated by our subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by us 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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