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): September 26, 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 September 26, 2024, Vivani Medical, Inc. (the "Company") announced it received regulatory approval to initiate a first in human clinical trial, known as the LIBERATE-1™, with the Company's GLP-1 (exenatide) implant in obese and overweight individuals in Australia. 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. onSeptember 26, 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: September 26, 2024

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Vivani Medical Receives Regulatory Approval to Initiate First in Human Clinical Trial with GLP-1 Implant in Obese and Overweight Individuals in Australia

NPM-115 clinical program utilizes a miniature, GLP-1 (exenatide) implant designed to provide comparable efficacy to semaglutide, the active ingredient in Ozempic®/Wegovy®, with twice- yearly administration

Study will represent the first clinical application of NanoPortal™, the Company's proprietary drug implant platform technology

ALAMEDA, Calif., September 26, 2024 -- (BUSINESS WIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), an innovative, biopharmaceutical company developing novel, ultra long-acting drug implants, today announced that the Bellberry Human Research Ethics Committee ("HREC") has approved and the Therapeutic Goods Administration ("TGA") in Australia has formally acknowledged a first in human clinical trial of the Company's miniature, subdermal GLP-1 (exenatide) implant in obese and overweight subjects. This clinical trial, known as LIBERATE-1™, will investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant and represents the first clinical application of the Company's proprietary NanoPortal™ drug implant technology.

"Securing regulatory approval keeps us on schedule to initiate this trial in Australia in the fourth quarter of 2024," said Adam Mendelsohn, Ph.D., Vivani President and Chief Executive Officer. "Preclinical weight loss and liver fat data announced earlier this year supports the potential for our GLP-1 implant to provide comparable efficacy to semaglutide, the active ingredient in blockbuster products Ozempic® and Wegovy®, but with the significant benefit of twice-yearly administration. We remain confident that our emerging portfolio of miniature, ultra long-acting, GLP-1 implants has the potential to be highly differentiated from the injectable and oral products in the market and in development. Specifically, our implants are uniquely designed to address medication non-adherence, a critical challenge for many patients which we believe represents the largest opportunity to improve real world health outcomes for patients, and the steady delivery of medicine enabled by our NanoPortal technology may also improve treatment tolerability."

LIBERATE-1 will be a randomized investigation of the safety, tolerability and pharmacokinetic profile of the exenatide NanoPortal implant in obese or overweight subjects. The trial will enroll participants who will 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 (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. Changes in weight will be measured. The trial is expected to be initiated later this year with data projected to be available in 2025.

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 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.

Ozempic® and Wegovy® are registered trademarks of Novo Nordisk A/S.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal TM platform, Vivani develops biopharmaceutical implantsdesigned 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, utilizes a miniature, six-month, subdermal, GLP-1 (exenatide) implant under development for the treatment of chronic weight management in obese or overweight individuals. Vivani's emerging pipeline also includes the NPM-139 (semaglutide) implant which is also under development for chronic weight management in obese and overweight individuals.
The semaglutide implant has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's Type 2 Diabetes development program utilizing a six-month, subdermal exenatide implant. Both the NPM-115 and NPM-119 programs utilize exenatide based products with a higher-dose associated with the NPM-115 program for chronic weight management in obese or overweight patients. 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 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.

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 initiation of the LIBERATE-1 trial and reporting of trial results, Vivani's emerging development plans for NPM-115, NPM-139, or Vivani's plans with respect to 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 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. 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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