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): June 7, 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 June 13, 2024, Vivani Medical, Inc. (the "Company") announced that the U.S. Food and Drug Administration (FDA) has lifted the full clinical hold and cleared the Company to initiate the LIBERATE-1™ Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of NPM-119 (exenatide), the Company's miniature, six-month GLP-1 implant in development for treatment of type 2 diabetes. 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 June 13, 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: June 13, 2024

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

Vivani Medical Announces FDA Clears Investigational New Drug Application and Lifts Clinical Hold for NPM-119, a Miniature Long-Term Subdermal GLP-1 Drug Implant

NPM-119 is being studied to address medication non-adherence and potentially improve tolerability issues associated with oral and injectable type 2 diabetes medications, by providing long-term therapeutic delivery of exenatide for six months

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

ALAMEDA, Calif., June 13, 2024 -- (BUSINESS WIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), an innovative, biopharmaceutical company developing novel, long-term drug implants, today announced the U.S. Food and Drug Administration has cleared the Investigational New Drug Application ("IND") and lifted the clinical hold on NPM-119 to allow initiation of LIBERATE-1™, a Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of NPM-119 (exenatide), the Company's miniature, six-month GLP-1 implant in development for the treatment of type 2 diabetes.

"Today marks a significant milestone for Vivani as we transition to a clinical-stage company with a promising drug candidate that has the potential to address medication non-adherence, which affects approximately 50% of patients with type 2 diabetes. LIBERATE-1 represents our first-in-human study of NPM-119 in type 2 diabetes patients, as well as the first clinical application of our innovative NanoPortal™ implant technology in humans," said Adam Mendelsohn, Ph.D., Vivani President and Chief Executive Officer. "This seminal work will characterize how NPM-119's promising preclinical pharmacokinetic profile translates to humans versus the marketed once-weekly exenatide active comparator, Bydureon BCise®."

Dr. Mendelsohn added: "The results of the study will also apply to our lead program, NPM-115, which is under development for chronic weight management and demonstrated weight loss comparable to injections of semaglutide, the active ingredient in blockbuster products Ozempic® and Wegovy®, in preclinical studies earlier this year. Subject to regulatory approval, we believe that NPM-115's six-month dosage form will make it an attractive and highly differentiated option within the extraordinarily large and rapidly growing obesity market. We are focused on final study preparations and anticipate initiating LIBERATE-1 during the second half of the year."

LIBERATE-1 is a randomized, 12-week investigation of the safety, tolerability, and full pharmacokinetic profile of NPM-119 in patients with type 2 diabetes. LIBERATE-1 will enroll patients who have previously received GLP-1 therapy, which will be discontinued prior to receiving either NPM-119 or the active comparator.

Vivani continues advancing its emerging pipeline of innovative, highly differentiated drug implants leveraging its proprietary NanoPortal™ subdermal implant technology, designed to guarantee medication adherence and improve patient outcomes in the treatment of chronic diseases such as chronic weight management and type 2 diabetes.

In addition to NPM-119 for the treatment of type 2 diabetes, Vivani is advancing the development of NPM-115 (high-dose exenatide implant) and NPM-139 (semaglutide implant), both promising treatments under development for chronic weight management. NPM-139 has the added potential for a once-yearly treatment duration.

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 tolerance to their medication. Vivani's lead programs, NPM-115 and NPM-119, are miniature, six-month, GLP-1 implants in development for the treatment of type 2 diabetes and chronic weight management in obese or overweight patients, respectively. Both NPM-115 and NPM-119 are exenatide based products with a higher-dose associated with NPM-115 for the treatment of 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.

Vivani's wholly owned subsidiary Cortigent is developing targeted neurostimulation systems intended to help patients recover critical body functions. Investigational devices include Orion®, designed to provide artificial vision to people who are profoundly blind, and a new system intended to accelerate the recovery of arm and hand function in patients who are partially paralyzed due to stroke. The company has developed, manufactured, and marketed an implantable visual prosthetic device, Argus II®, that delivered meaningful visual perception to blind individuals. Vivani continues to assess strategic options for advancing Cortigent's pioneering technology.

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, NPM-139, or our plans with respect to Cortigent and its proposed initial public offering, 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 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 NPM-115 and NPM-119; 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 commence clinical development of NPM-119; 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 SEC 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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