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 4, 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 4, 2024, Vivani Medical, Inc. (the "Company") announced positive preclinical liver fat results with the Company's GLP-1 (exenatide) implant. The clinical development of the Company's GLP-1 (exenatide) implant in overweight and obese patients as part of the Company'sNPM-115 program remains on track to commence in the fourth quarter of 2024. 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 4, 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 4, 2024

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Vivani Medical Announces Positive Preclinical Liver Fat Results with Miniature, Ultra Long-Acting GLP-1 Implant

Vivani's GLP-1 (exenatide) implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing

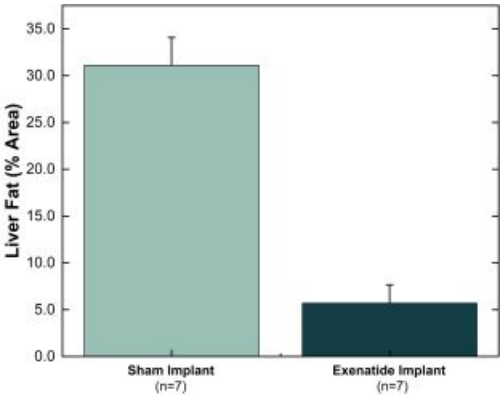
Vivani previously announced sham-implant adjusted preclinical weight loss of 20%, which is comparable to the weight loss produced from the semaglutide (active ingredient in Ozempic®/Wegovy®) injection control arm in the same study

Clinical development of Vivani's exenatide implant in overweight and obese patients as part of the Company's NPM-115 program remains on track to commence in the fourth quarter of 2024

ALAMEDA, Calif., September 4, 2024 -- (BUSINESS WIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), an innovative biopharmaceutical company developing miniature, ultra long-acting, subdermal drug implants, today reported positive preclinical liver fat results with its exenatide implant.

"The reduction in liver fat observed preclinically with our miniature, subdermal exenatide implant, provides further support that the NanoPortal™ implant technology continues to hold great potential as a highly differentiated treatment option for the treatment of obesity and chronic weight management as well as related metabolic disorders," said Adam Mendelsohn, Ph.D., Vivani President and Chief Executive Officer. "While the currently marketed GLP-1 based drugs have made profound improvements in the treatment of chronic diseases, including obesity and chronic weight management, significant barriers to optimal patient outcomes persist due to medication non-adherence and poor tolerability. We remain committed to the development of our portfolio of innovative, miniature, GLP-1 implant candidates and their potential to improve real-world patient outcomes by improving medication adherence. In addition, we believe that our implant's minimally fluctuating release profile combined with avoiding inevitable drug fluctuations that result from poor adherence may have the potential to improve treatment tolerability, a primary complaint associated with currently available GLP-1 treatment options. Our first clinical study, LIBERATE-1™, is anticipated to start in the fourth quarter of 2024 with results in 2025."

Liver Fat Reduction in High Fat Diet-induced Obese Mice

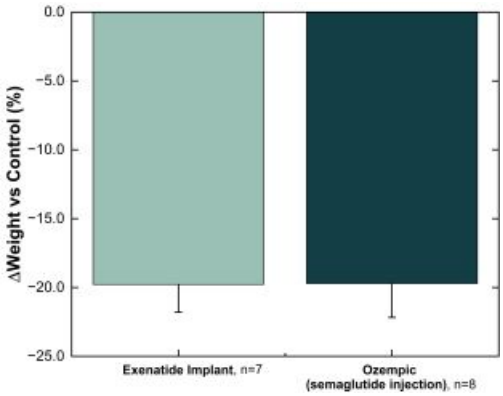


Liver fat % area for exenatide implant vs sham implant 12 weeks after a single administration. Liver fat % area is calculated using Oil Red O (ORO) staining. Values are mean ± SE.

These liver fat data are consistent with published results from similar investigations with semaglutide, the active pharmaceutical ingredient in Ozempic and Wegovy.

Previously reported results from this study in high-fat diet-induced obese mice demonstrated that Vivani's exenatide implant generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to the weight loss observed in the semaglutide active control arm in the study. The supratherapeutic doses provided for the exenatide implant (single administration delivering exenatide at ~530 nmol/kg/day) and semaglutide (weekly injections of ~2,700 nmol/kg/week) were selected to maximize the weight-loss potential of both exenatide and semaglutide.

Weight Loss in High Fat Diet-induced Obese Mice



% weight change from baseline for exenatide implant vs semaglutide injections after a 28-day treatment duration, corrected to control (sham implant). Values are mean ± SE.

NPM-115 Program

In July 2024, Vivani provided an update on the clinical development plans forits obesity program, NPM-115, which will evaluate the Company's miniature, long-acting exenatide implant in obese and overweight patients. In support of the recent strategic shift to prioritize the development of its obesity and chronic weight management portfolio, the Company announced revised plans to evaluate its GLP-1 implant as part of the NPM-115 program in individuals who are obese or overweight in the Company's first-in-human study, LIBERATE-1. This study will enroll participants who will be titrated on weekly semaglutide (Wegovy) for eight weeks before being randomized to receive a single exenatide implant, weekly exenatide injections (Bydureon BCise®), or weekly semaglutide injections for a nine-week treatment duration. The Company expects the study to be initiated in the fourth quarter of 2024 in Australia, pending regulatory approval, with data from the study anticipated in 2025.

Ozempic® and Wegovy® are a registered trademarks of Novo Nordisk A/S.
Bydureon BCise® is a registered trademark of the AstraZeneca group of companies.

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 program, NPM-115, will evaluate a miniature, six-month, subdermal, GLP-1 (exenatide) implant for chronic weight management in obese or overweight individuals. Vivani's emerging pipeline also includes NPM-139 (semaglutide implant) which is also under development for chronic weight management in obese and overweight patients. NPM-139 has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's clinical program which will evaluate itssix-month, subdermal exenatide implant for the treatment of type 2 diabetes. These NanoPortal implants are designed to provide individuals 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 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 individuals, and those taking treatments for type 2 diabetes or other chronic diseases, face significant challenges in achieving positive real-world effectiveness. While the current GLP-1 landscape includes over50 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, and NPM-119. 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, including Vivani's ability to commence clinical development of NPM-115; 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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