

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): August 17, 2026

Vivani Medical, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36747
(Commission
File Number)

02-0692322
(IRS Employer
Identification No.)

1350 S. Loop Road
Alameda, California
(Address of principal executive offices)

94502
(Zip Code)

Registrant's telephone number, including area code: (415) 506-8462

N/A

(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 7.01. Regulation FD Disclosure.

Vivani Medical, Inc. ("Vivani") from time to time presents, and/or distributes to the investment community at various industry and other conferences, slide presentations to provide updates and summaries of its business. A copy of these slides is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein. The slide presentation speaks only as of the date of this Current Report on Form 8-K. While Vivani may elect to update the slide presentation in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, Vivani specifically disclaims any obligation to do so.

The information contained in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, or otherwise subject to the liabilities under that Section. Furthermore, the information contained in this Item 7.01 and Exhibit 99.1 shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Vivani Medical, Inc. slide presentation dated August 17, 2026.
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 hereunto duly authorized.

VIVANI MEDICAL, INC.

Date: August 17, 2026

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



Vivani Medical, Inc.

Guaranteed Adherence.
Better Outcomes.

www.vivani.com



August 17, 2026

Disclaimers

The following slides and any accompanying oral presentation contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the "safe harbor" created by those sections. All statements in this release that are not based on historical fact are "forward looking statements." These statements may be identified by words such as "estimates," "anticipates," "projects," "plans" or "planned," "strategy," "goal," "seeks," "may," "will," "expects," "intends," "believes," "should," and similar expressions, or the negative versions thereof, and which also may be identified by their context. All statements that address operating performance or events or developments that Vivani Medical, Inc. ("Vivani", the "Company", "we" or "us") expects or anticipates will occur in the future, such as stated objectives or goals, our products and their therapeutic potential and planned development, the indications that we intend to target, our technology, our business and strategy, milestones, addressable markets, or that are not otherwise historical facts, are forward-looking statements. While management has based any forward-looking statements included in this presentation on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements as a result of various factors. These risks and uncertainties include, but are not limited to, that we may fail to commence our planned future clinical trials for products under development; conduct any pre-clinical activities of our other products; our products may not demonstrate safety or efficacy in clinical trials; we may fail to secure marketing approvals for our products; there may be delays in regulatory approval or changes in regulatory framework that are out of our control; our estimation of addressable markets of our products may be inaccurate; we may fail to timely raise additional required funding; more efficient competitors or more effective competing treatment may emerge; we may be involved in disputes surrounding the use of our intellectual property crucial to our success; we may not be able to attract and retain key employees and qualified personnel; earlier study results may not be predictive of later stage study outcomes; and we are dependent on third-parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks and uncertainties are described in our Annual Report on Form 10-K filed on March 26, 2026, our Quarterly Report on Form 10-Q filed on August 13, 2026, and our subsequent filings with the U.S. Securities and Exchange Commission. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto, or any change in events, conditions, or circumstances on which any such statement is based.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third party sources and the Company's own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source. All of our therapies are still investigational and have not been approved by any regulatory authority for any use.



The obesity market is evolving

What will it take to be successful in the future?

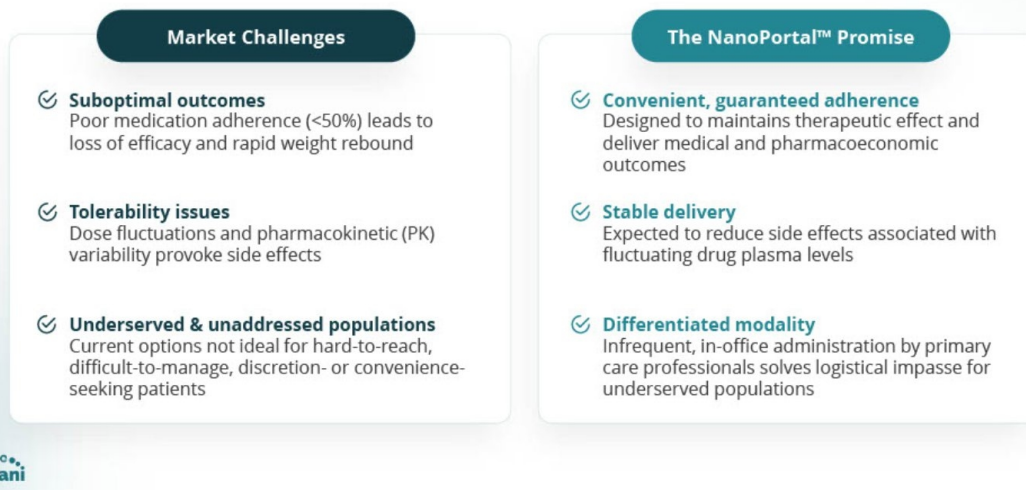
In addition to the currently FDA-approved products on the market, there are over 50 in clinical development. All of these are injectables or orals. Vivani's implant uniquely combines infrequent (e.g., once- or twice-yearly) administration with the ability to stop treatment quickly, if necessary.

A differentiated route of administration presents opportunities to access untapped segments of this market, transition experienced patients to a longer-acting option, and help patients struggling with adherence to have access to a guaranteed-adherence option.



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Vivani's differentiated product candidates are designed to address unmet needs and expand the market



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Vivani Medical, Inc.

A clinical stage innovator uniquely positioned to address the future challenges and opportunities of an evolving obesity market

- Our focus:** Enhance patient outcomes and GLP-1 market uptake in chronic diseases via unique route of administration, improved patient adherence, tolerability, and convenience
- Technology:** NanoPortal ultra long-acting, miniature drug implants designed to enable very infrequent dosing, including every 6 months, 12 months, or longer
- Lead program:** NPM-139 is a miniature, subdermal, semaglutide implant for chronic weight management in obese and overweight individuals
- Clinical catalysts ahead:** SLIM-1 (semaglutide implant) rapidly enrolled with all patients dosed; top-line data expected in Nov 2026; Phase 2 design underway for anticipated 2027 start
- Platform Proof of Concept:** Preclinical weight loss of ~20% sustained for a full year

Nasdaq: VANI

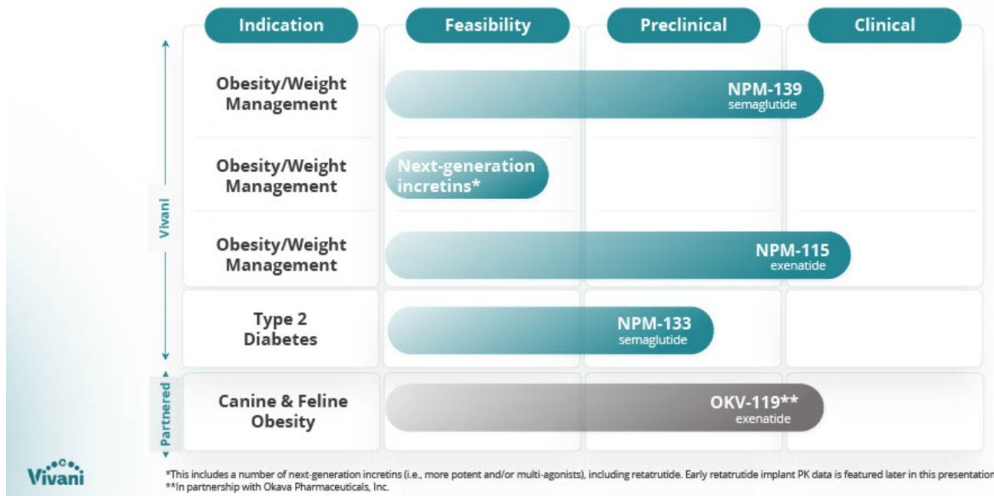
- ✓ Cash runway expected to fund current operating plan, including completion of key milestones, through 1H2027
- ✓ SLIM-1 clinical study (NPM-139, semaglutide implant) and Novo Nordisk evaluation ongoing
- ✓ Highly specialized & proprietary manufacturing operations in Alameda, CA

GLP-1 market expected to grow to \$190B by 2035*

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Company pipeline utilizing NanoPortal platform

If approved, Vivani products would provide a differentiated ultra long-acting option for patients



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Good things come in small packages

01 GLP-1 implant & applicator

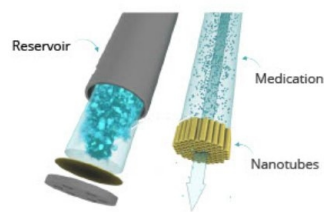


- ✓ Simple administration, in-office procedure to insert the implant comfortably under the skin for twice-yearly dosing designed to produce Wegovy®-level efficacy



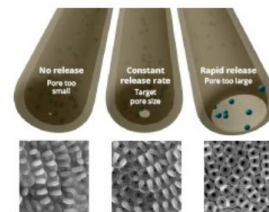
02 NanoPortal device elements

- ✓ Designed to assure adherence
- ✓ Long-term delivery
- ✓ Stable and tunable release profile



03 NanoPortal technology

- ✓ Nanotube pore size is precisely tunable to achieve near-constant release profiles

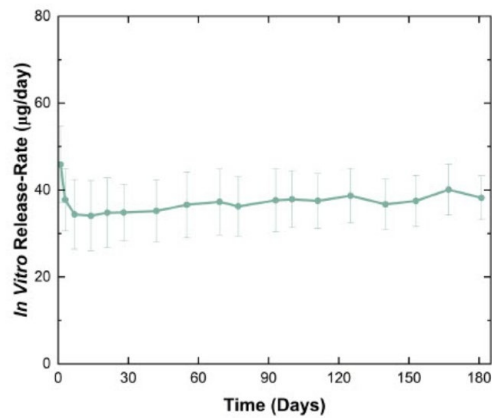


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NanoPortal delivers smooth, near-constant drug release

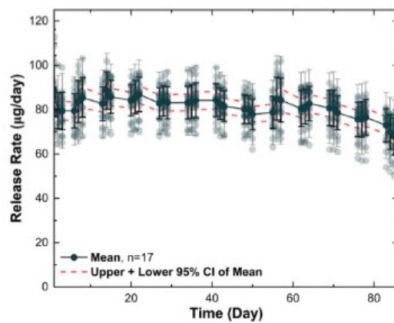
Day 1 timepoint includes cumulative release over the first day including a separately measured 1st hour of release, which was ~7 µg for the high-dose and ~4 µg for the low-dose. Values are mean ± SD.

*Release-rates include exenatide and related substances.

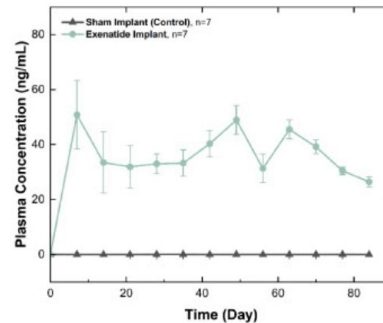


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In vitro and in vivo performance of 12-week GLP-1 implant configuration



In vitro release-rate of exenatide implant (n=17). Individual values are included for each timepoint. Each week consists of two 24-hour intervals and a 5-day interval. Values are mean ± 1 SD (bold) and ± 2 SD. Release-rates include exenatide and related substances.

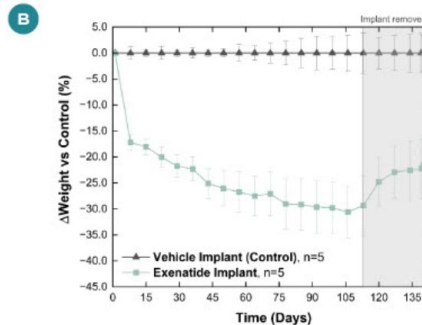
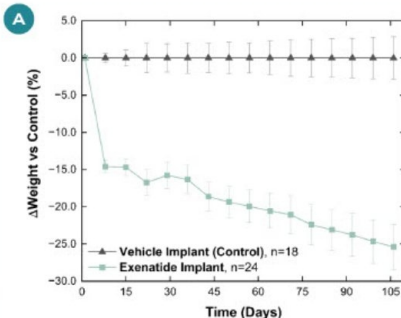


In vivo pharmacokinetics of 12-week exenatide implant and sham implant in high fat diet-induced obese mice (n=7 per group). Values are mean ± SE.

Day 56 values reported as measured, but sample handling error suspected to have occurred.

9

Preclinical GLP-1 NanoPortal implant is associated with durable body weight effects



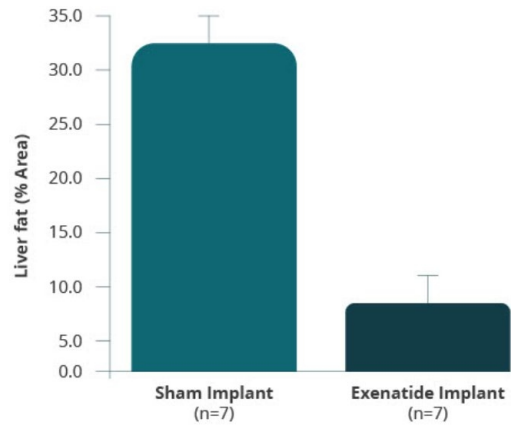
Weight difference from control in healthy Sprague-Dawley Rats. % weight change from baseline for a single administration of exenatide implant in a study associated with NPM-119 (~320 nmol/kg/day) corrected to control (vehicle implant). (A) All animals measured through 105 days of treatment; (B) 5 animals measured in each group through 112 days of treatment followed by a 28-day recovery period. Values are mean ± SE.



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GLP-1 NanoPortal implant reduced liver fat by 82% in preclinical study

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. Values are mean $\pm$ SE.



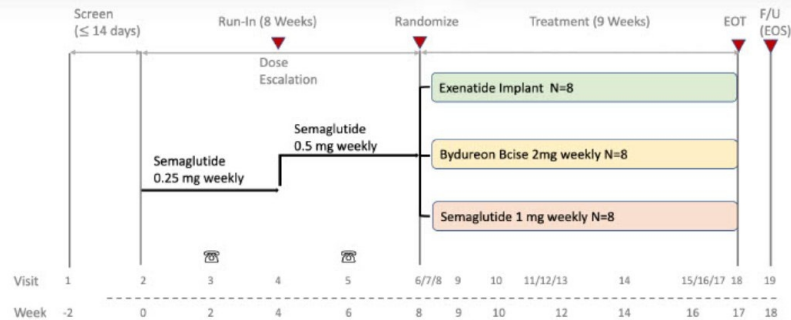
First-in-human GLP-1 NanoPortal clinical trial: LIBERATE-1

Primary Objectives

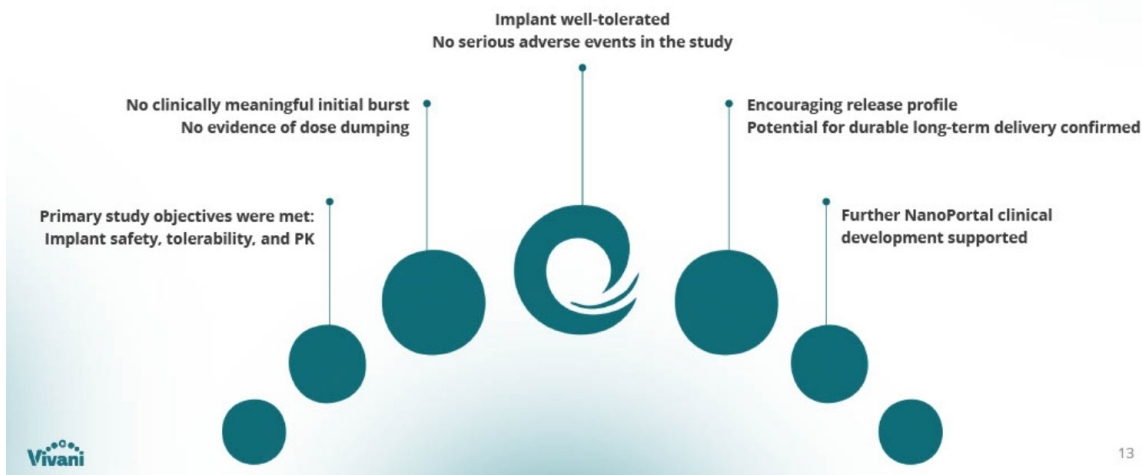
Safety/tolerability assessment and full pharmacokinetic characterization. Changes in weight also assessed.

Key Inclusion/Exclusion Criteria

18-55 years old; overweight or obese (BMI 27-40)
Otherwise healthy (no T2D, normal renal function)



LIBERATE-1 topline results summary



Vivani Lead Program: NPM-139

SLIM™: Semaglutide ultra Long-acting IMplant in obesity



Priority clinical development program: NPM-139

Development of once- or twice-yearly semaglutide implant for chronic weight management in obese or overweight patients



FDA-approved GLP-1 products generated **\$132B** in global sales in 2025. The market for FDA-approved GLP-1 products for weight loss is expected to grow at a 131% CAGR.¹



Based on real-world adherence and persistence data, **>50%** of patients regularly miss doses; **>50%** discontinue by year 1 and **~75%** discontinue by year 2²



The initial program activities are being designed to support additional semaglutide applications such as **type 2 diabetes** (NPM-133), **CKD in type 2 diabetes**, **MASH, alcohol and other addictions, etc.**



¹ Morgan Stanley. (2026, April). "Obesity Drugs Are Scaling Fast." <https://www.morganstanley.com/insights/articles/glp1-weight-loss-market-may-double-190-billion-2035>
² Gleason, P. P., Urlick, B. Y., Marshall, L. Z., Friedlander, N., Qiu, Y., & Leslie, R. S. (2024). Real-world persistence and adherence to glucagon-like peptide-1 receptor agonists among obese commercially insured adults without diabetes. *Journal of managed care & specialty pharmacy*, 30(8), 860-867. <https://doi.org/10.18553/jmcp.2024.23332>

Persistence and adherence are critical to securing desired long-term health outcomes

Persistence data comparing obesity therapies suggest room for improvement across the board, including for semaglutide. The unmet need is significant.

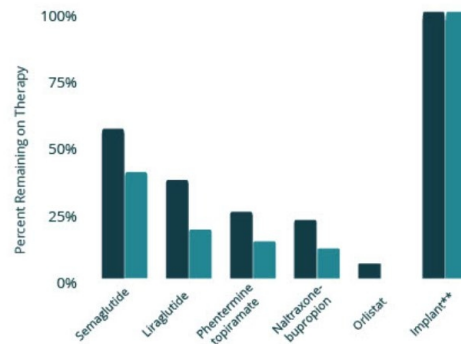
- ✓ The opportunity for an additional 60% improvement in persistence for semaglutide is remarkable and could translate to improved patient outcomes
- ✓ Semaglutide implant is designed to guarantee adherence during the entire once- or twice-yearly dosing interval



* Published in Obesity, December 8, 2023

Large Retrospective Cohort Study* (N=1,911)

■ 6 months ■ 12 months

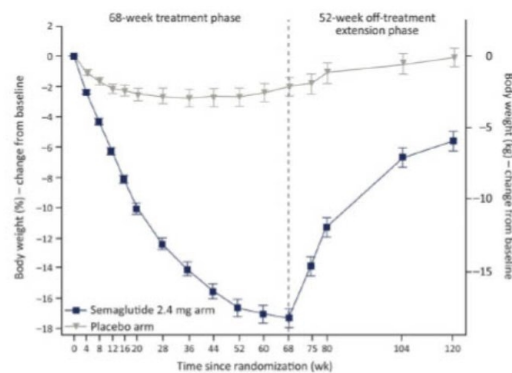


** Implant not included in this Large Retrospective Cohort Study, included for illustrative purposes only; assumes full replacement at 6 months

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Semaglutide discontinuation leads to rapid hunger-induced weight rebound

Sudden GLP-1 withdrawal produces immediate rebound hunger, leading to rapid weight regain mediated by greater food consumption



STEP 1 Extension: Semaglutide Withdrawal From Novo Nordisk Wegovy® Clinical Program

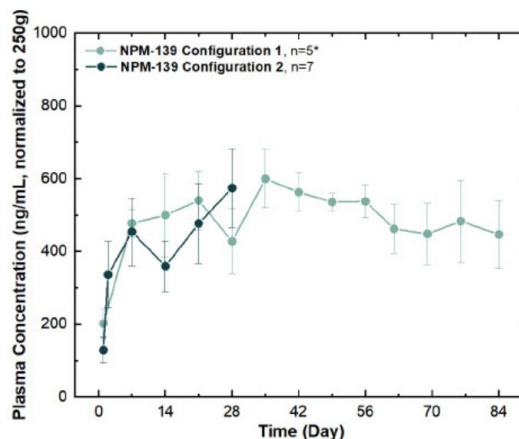


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NPM-139 provides steady preclinical pharmacokinetics

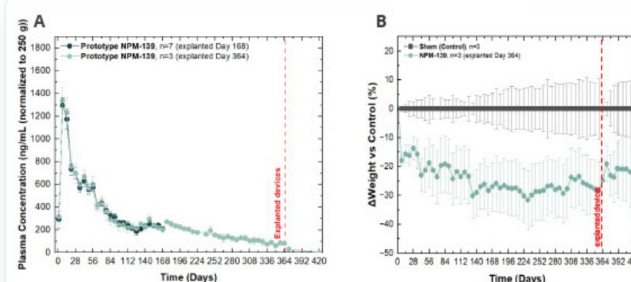
In vivo pharmacokinetics of NPM-139 configurations in Sprague-Dawley rats. Values are mean $\pm$ SE.

*n=5 through day 28; two implants removed at Day 28 for characterization, n=3 thereafter.



Prototype semaglutide NanoPortal implant demonstrates sustained weight loss and delivery for a full year

Prototype NPM-139, prior to PK optimization. *In Vivo* Pharmacokinetics and Weight loss vs. control in Sprague-Dawley Rats (A). % weight loss from baseline normalized to a sham-implant control (B). Values are mean $\pm$ SE.



Normalized semaglutide plasma concentrations remain measurable throughout the entire 364-day duration. Implant removal results in immediate decline in plasma levels, as expected.

Patient and prescriber market research signals strong adoption potential for an ultra-long-acting GLP-1 implant

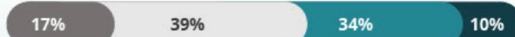
Currently on a GLP-1 therapy (n=324)



Ex-GLP-1 therapy (n=178)



GLP-1 therapy naïve (n=319)



● Definitely not ● Unlikely ● Likely ● Definitely

dQ&A Insights reported market research during FDA Advisory Board to review ITCA 650 (exenatide implant) on September 21, 2023. Research conducted in patients with T2D.

Patient market research

56% of GLP-1 patients responded "likely" or "definitely" to get a GLP-1 implant if FDA approved, prescriber recommended, and covered by insurance

Prescriber market research

Average prescriber rating of **8.3 on a 10-point scale** regarding likelihood of prescribing a long-acting GLP-1 implant

Vivani sponsored qualitative (n=10) market research of diabetes treating primary care physicians, March 2020. ~90% of patients receive treatment in primary care.

Contraception analog provides further support for the commercial potential for a miniature GLP-1 implant

THE CONTRACEPTION MARKET: AN ANALOG FOR GLP-1s

Both require chronic dosing, with therapeutic options spanning oral pills and long-acting implants. Among U.S. women using a drug or device for contraception:



~90% of women using prescription contraceptive drugs or devices choose one of these two categories.

*Nexplanon demonstrates commercial potential for a subdermal implant in primary care (~\$1B in annual sales).



Contraception: Daniels K, Abma JC. Current Contraceptive Status Among Females Ages 15–49: United States, 2022–2023. NCHS Data Brief No. 539, National Center for Health Statistics, 2025. Organon reported Nexplanon sales, FY 2025.

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NPM-139 clinical and regulatory development: Near-term plan builds on recent wins

Milestone	Status
Reported preclinical proof of concept (~20% weight loss) with NPM-139 (semaglutide implant)	August 2025
Received regulatory approval to initiate SLIM-1 clinical trial	June 2026
Announced Novo Nordisk agreement to evaluate NPM-139	July 2026
SLIM-1 full enrollment and all patients successfully dosed	August 2026
Report SLIM-1™, Phase 1 trial, top-line Results	November 2026 (projected)
Initiation of Phase 2 dose ranging study	2027 (projected)



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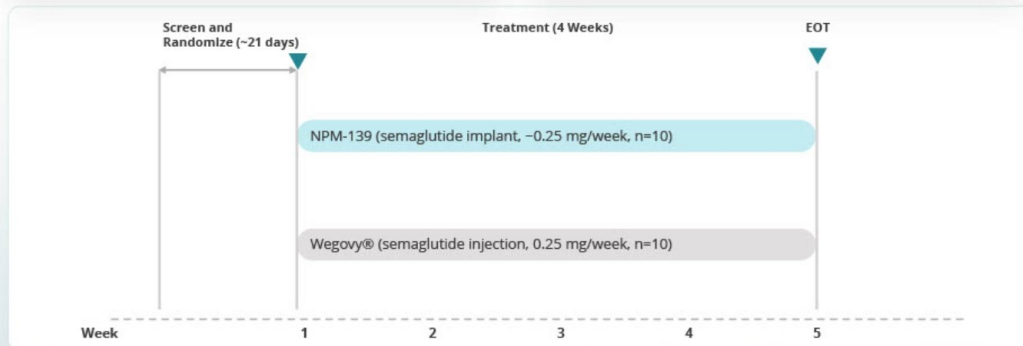
NPM-139 Phase 1 study design: SLIM-1™

Primary Objectives

Safety/tolerability assessment and pharmacokinetic characterization

Key Inclusion/Exclusion Criteria

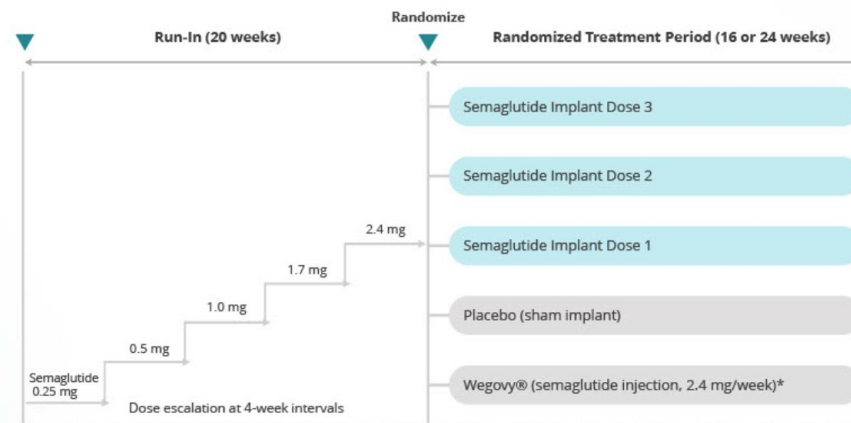
18-55 years old; overweight or obese (BMI 27-40)
Otherwise healthy (no T2D)



T2D = Type 2 Diabetes; EOT = End of Treatment

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Proposed NPM-139 Phase 2 study design: SLIM-2™

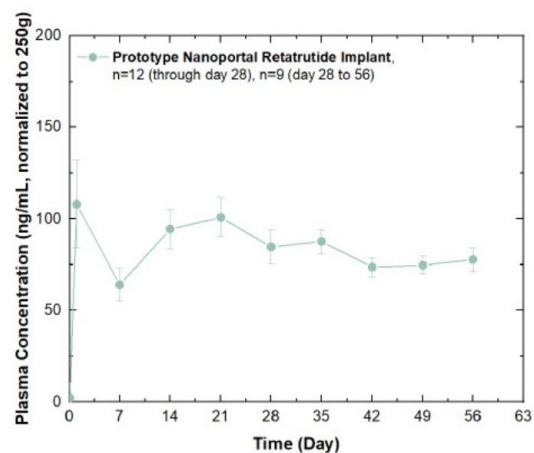


*unblinded

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NanoPortal retatrutide implant provides steady preclinical pharmacokinetics in ongoing study

In vivo pharmacokinetics of prototype NanoPortal retatrutide implant in Sprague-Dawley rats in an ongoing study. Values are mean $\pm$ SE.



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Vivani headquarters and GMP manufacturing facility



The Vivani executive leadership team



Adam Mendelsohn PhD
CEO/Director

- ✓ Co-founder/Co-inventor of Vivani technology
- ✓ PhD Bioengineering (UCSF/UC Berkeley)
- ✓ Management of Technology Certificate at Haas School of Business
- ✓ Research focused on diabetes treatment
- ✓ Formerly at Boston Scientific and MiniMed



Donald Dwyer, MBA
Chief Business Officer

- ✓ Former Executive Director at AstraZeneca with leadership roles in regulatory affairs, drug development, commercial and business development
- ✓ Former Vivani Board observer for AZ
- ✓ Former PhaseBio Board observer for AZ (prior to IPO)
- ✓ Former Director at Cephalon and Rhone Poulenc Rorer



Lisa Porter, MD
Chief Medical Officer

- ✓ Former Chief Medical Officer for Eisai BioPharmaceuticals and Dance BioPharm
- ✓ Former VP of Medical Development for Amgen
- ✓ Former Director at GSK, Global Head of Clinical Strategy for Avandia
- ✓ Former Board member of ViaCyte, Inc.



Truc Le, MBA
Chief Operations Officer

- ✓ Numerous COO and Executive Positions at Device and Drug-Device Companies, including:
- ✓ CTO at Dance BioPharm, COO at Avid Bio
- ✓ Exec VP at Prima Biomed, Sr. VP at Nektar Therapeutics (responsible for Exubera approval), and Worldwide VP at Johnson & Johnson



Anthony Baldor, MS, MBA
Chief Financial Officer

- ✓ Former CFO and Head of Business Development at Diakonos Oncology
- ✓ Former VP Corporate Strategy and Development at ADMT
- ✓ Former Research Analyst at Jefferies
- ✓ Former Venture Capital Principal at BiolInnovation Capital and Associate at RMI Partners

Guaranteed adherence. Improved outcomes.

- ✓ Only GLP-1 implant in development for obesity and chronic weight management
- ✓ Convenient once- or twice-yearly dosing expected to address primary GLP-1 market challenges
- ✓ Unique modality designed to reach underserved & unaddressed populations key to market expansion



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Thank You

Company Contact:
Donald Dwyer, Chief Business Officer
info@vivani.com

Investor Relations Contact:
Jami Taylor, Investor Relations Advisor
investors@vivani.com

www.vivani.com

