
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 9, 2025

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 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	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. (the “Company”) 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. These slides are attached to this Current Report on Form 8-K as Exhibit 99.1 and are incorporated by reference herein. The Company is also posting to the “Investors” portion of its website a copy of its current corporate slide presentation. The slides speak as of the date of this Current Report on Form 8-K. While the Company may elect to update the slides in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so.

The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Securities Act, whether made before or after the date hereof, 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	Corporate Slides as of September 9, 2025.
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 9, 2025

By: /s/ Donald Dwyer

Name: Donald Dwyer

Title: Chief Business Officer



Vivani Medical, Inc.

Guaranteed Adherence.
Better Outcomes.

www.vivani.com



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 31, 2025, 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 two approved products on the market, there are over 50 in clinical development. All of these are injectables or orals.

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.



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

Market Challenges

- ✓ **Suboptimal outcomes**
Poor medication adherence (<50%) leads to loss of efficacy and rapid weight rebound
- ✓ **Tolerability issues**
Dose fluctuations and pharmacokinetic (PK) variability provoke side effects
- ✓ **Pricing & access challenges**
13+ devices/year drive higher cost of goods, reducing pricing flexibility with subcutaneous (SC) dosing
- ✓ **Underserved & unaddressed populations**
Current options not ideal for hard-to-reach, difficult-to-manage, discretion- or convenience-seeking patients

The NanoPortal™ Promise

- ✓ **Convenient, guaranteed adherence**
Maintains therapeutic effect and delivers medical and pharmacoeconomic outcomes
- ✓ **Stable delivery**
Expected to reduce side effects associated with fluctuating drug plasma levels
- ✓ **Lower costs and pricing flexibility**
1-2 devices/year results in lower cost of goods vs. SC dosing, providing greater pricing flexibility
- ✓ **Differentiated modality**
Infrequent, in-office administration by primary care professionals reaches underserved populations

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 dosing every 6 to 12 months



Lead program: NPM-139 is a miniature, subdermal, semaglutide implant for chronic weight management in obese and overweight individuals



Clinical success: LIBERATE-1 first-in-human study achieved the primary objectives including positive safety, tolerability and device performance



Platform Proof of Concept: Preclinical weight loss of ~20% sustained at 7 months in an ongoing study



*TD Cowen (M. Nedelcovych, S. Scala, C. Rhyee, Y. Werber, E. McAllister), "GLP-1 Market: The Pipeline Expands," March 2025.

Nasdaq: VANI

- ✓ Cash runway through key milestones and into 2H26
- ✓ NPM-139 clinical program initiation in 1H 2026
- ✓ Manufacturing & operations in Alameda, CA

GLP-1 Market expected to grow to \$139B by 2030*

Company pipeline utilizing NanoPortal platform

If approved, Vivani products may compete in markets with large commercial potential

	Indication	Feasibility	Pre-Clinical	Clinical	Market Size**
Vivani	Obesity/Weight Management		NPM-139* semaglutide		>\$60B
	Type 2 Diabetes		NPM-133 semaglutide		>\$60B
	Obesity/Weight Management		NPM-115 exenatide		>\$60B
Partnered	Canine & Feline Obesity		OKV-119*** exenatide		>\$2B

*Feasibility recently established with semaglutide, supporting priority development.

**Estimated Market Sizes where Vivani products would compete, if approved. Does not represent future sales or revenue estimates of Vivani pipeline products.

TD Cowen estimates \$139B in GLP-1 sales by 2030. We assume >\$60B for Obesity/Chronic Weight Management and >\$60B for Type 2 Diabetes by 2030.

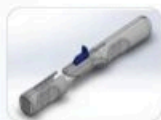
*** In Partnership with Okava Pharmaceuticals, Inc. Market size estimate based on Okava internal analysis.

Good things come in small packages

01 GLP-1 implant & applicator



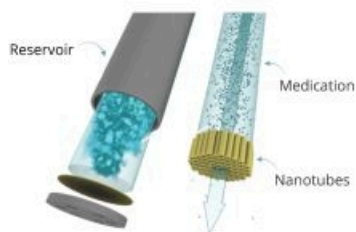
- ✓ Simple administration, in-office procedure to insert the implant comfortably under the skin for twice-yearly dosing designed to produce Wegovy®-level efficacy



Vivani

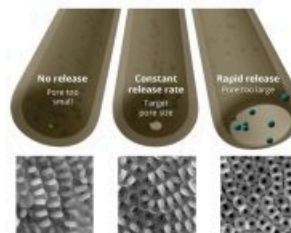
02 NanoPortal device elements

- ✓ 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

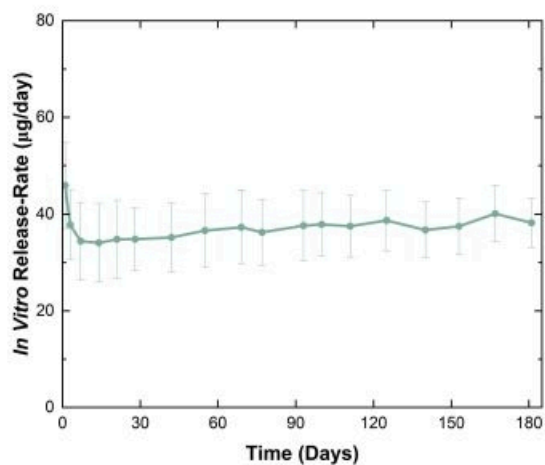


NanoPortal delivers smooth, near-constant drug release

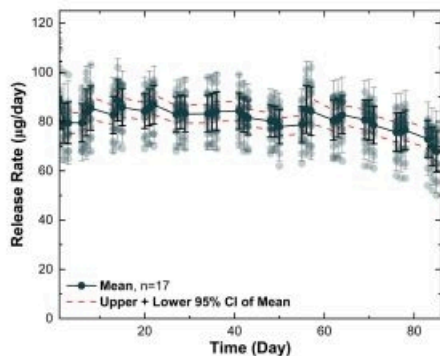
In vitro release-rate of exenatide implant (n=6).

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.

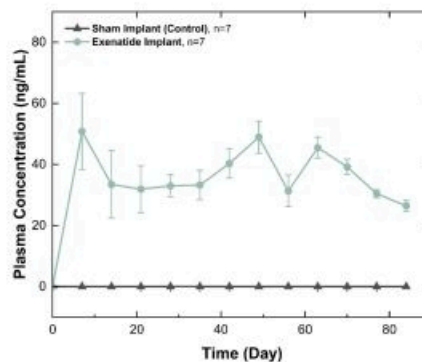
*Release-rates include exenatide and related substances.



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 \pm 1 SD (bold) and \pm 2 SD. Release-rates include exenatide and related substances.

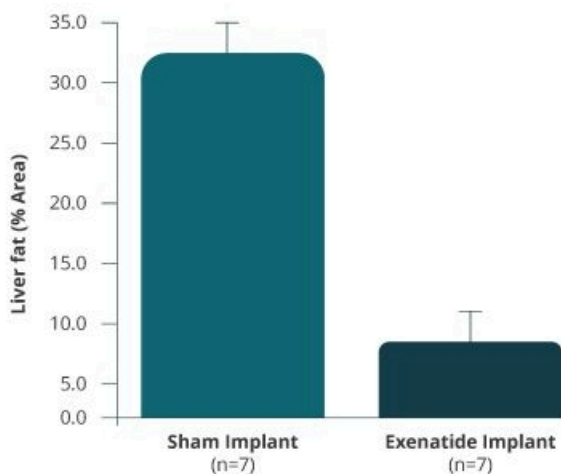


In vivo pharmacokinetics of 12-week exenatide implant and sham implant in high fat diet-induced obese mice (n=7 per group). Values are mean \pm SE.

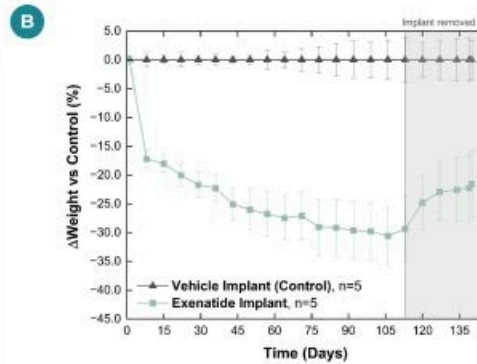
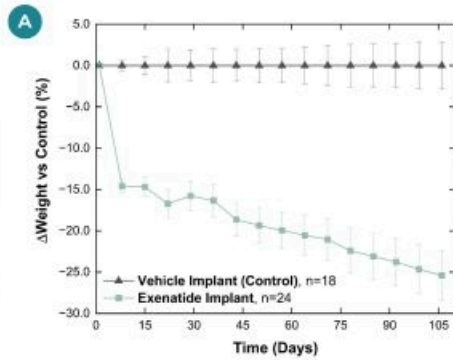
Day 56 values reported as measured, but sample handling error suspected to have occurred.

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.



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 \pm SE.

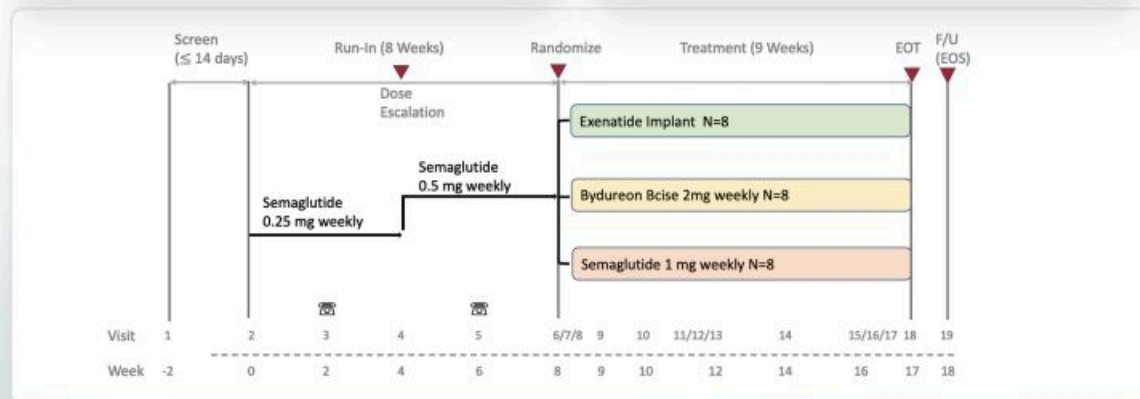
First-in-human GLP-1 NanoPortal clinical trial: LIBERATE-1

Primary Objectives

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

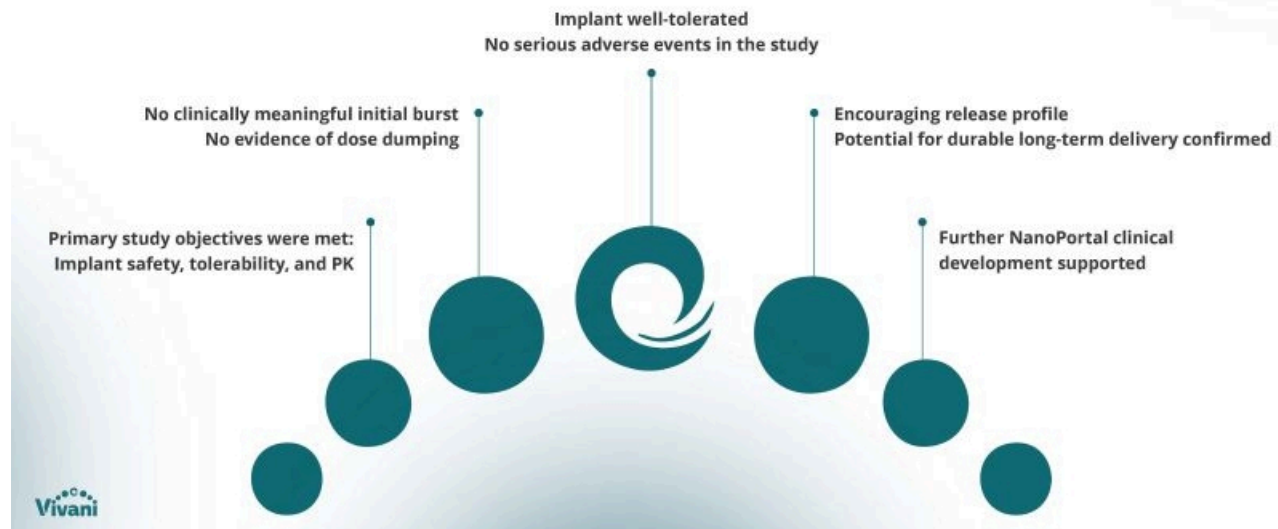
Key Inclusion/Exclusion Criteria

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



T2D = Type 2 Diabetes; EOT = End of Treatment; EOS = End of Study

LIBERATE-1 topline results summary



Vivani Lead Program: NPM-139

Semaglutide Implant for
Chronic Weight Management

Targeting the Rapidly Growing GLP-1 Market



Priority clinical development program: NPM-139

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



GLP-1 products generated **>\$14B** in sales in 2024 for chronic weight management. The obesity market is expected to grow at **~32% 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**, **Alzheimer's**, **alcohol addiction**, etc.

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

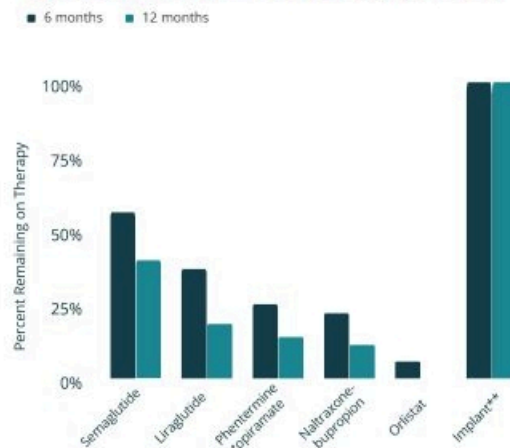
Persistence data comparing obesity therapies suggest room for improvement across the board, including for semaglutide.

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



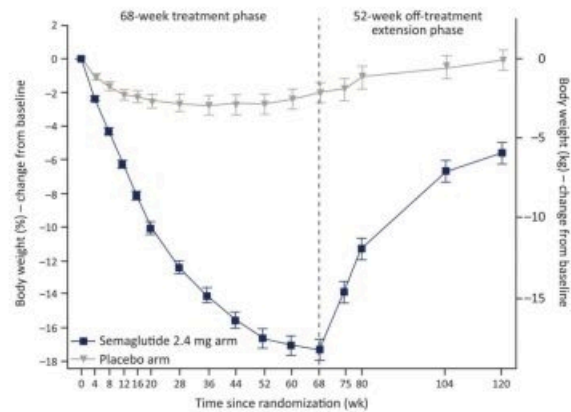
* Published in Obesity, December 8, 2023

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



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

Semaglutide discontinuation leads to rapid hunger-induced weight rebound

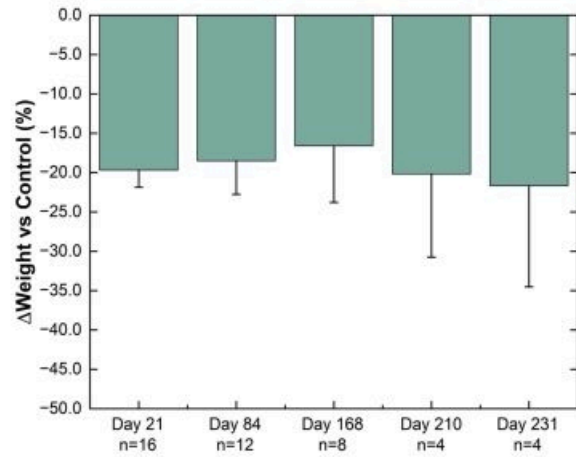


STEP 1 Extension: Semaglutide Withdrawal

Wilding et al., 2022, Diabetes, Obesity, and Metabolism

Semaglutide implant successfully delivers durable weight loss in preclinical model for >7 months

Weight difference versus control group in healthy Sprague-Dawley rats. % weight change from baseline for NPM-139 (semaglutide implant) corrected to control (sham implant). Implants from 4 animals were removed on each of Day 21, Day 84, and Day 168 for characterization. Values are mean \pm SE.



Patient and prescriber research indicates strong adoption potential for a miniature, 6-month GLP-1 implant

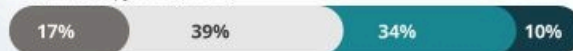
Currently on a GLP-1 therapy (n=324)



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



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

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

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

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

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

Milestone	Status
Announced LIBERATE-1 completed and met the primary study objectives	August 2025
Reported positive weight loss in preclinical study with semaglutide implant	August 2025
Disclosed proposed clinical program including Phase 1 PK and Phase 2 dose-ranging weight maintenance studies	September 2025
Initiate NPM-139 clinical program	1H 2026 (projected)

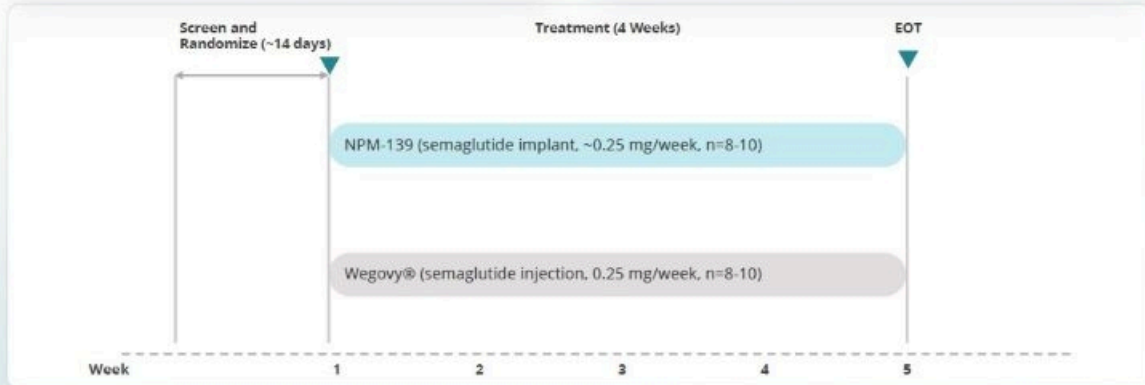
Proposed NPM-139 Phase 1 study design

Primary Objectives

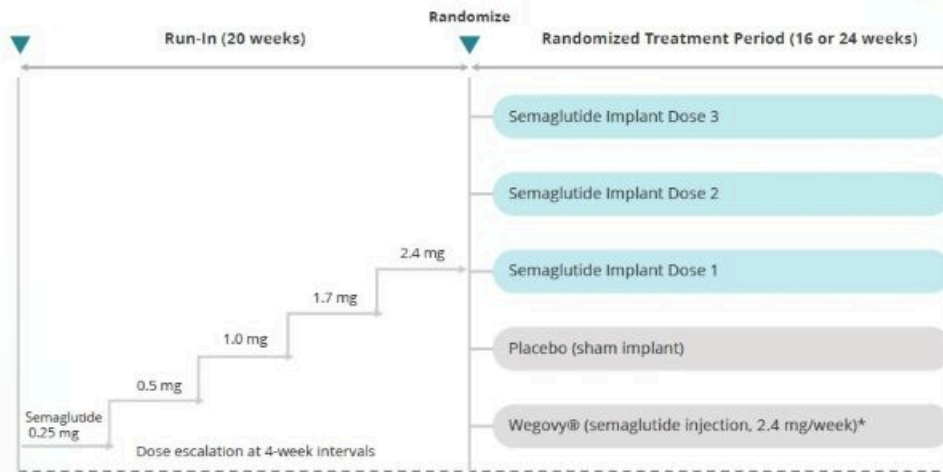
Safety/tolerability assessment and pharmacokinetic characterization

Key Inclusion/Exclusion Criteria

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



Proposed NPM-139 Phase 2 study design



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 Elger BioPharmaceuticals and Dance BioPharm
- ✓ Former VP of Medical Development for Amylin
- ✓ Former Director at GSK, Global Head of Clinical Strategy for Avandia
- ✓ Former Board member of ViaCyt, Inc.



Truc Le, MBA
Chief Operations Officer

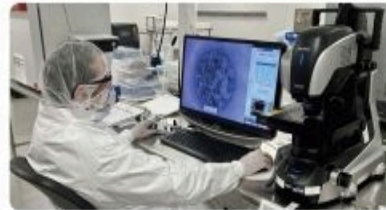
- ✓ Numerous COO and Executive Positions at Device and Drug-Device Companies, including:
- ✓ CTO at Dance BioPharm, COO at Avid Bio
- ✓ Exec VP at Prima Biomed, Sr. VP at Nektar Therapeutics (responsible for Exubera approval), and Worldwide VP at Johnson & Johnson



Anthony Baldor, MS, MBA
Chief Financial Officer

- ✓ Former CFO and Head of Business Development at Diakonos Oncology
- ✓ Former VP Corporate Strategy and Development at 4DMT
- ✓ Former Research Analyst at Jefferies
- ✓ Former Venture Capital Principal at BioInnovation Capital and Associate at RMI Partners

Vivani headquarters and GMP manufacturing facility



Guaranteed adherence. Improved outcomes.

- ✓ Only GLP-1 implant in development
- ✓ Convenient once- or twice-yearly dosing expected to address GLP-1 adherence and tolerability challenges
- ✓ Unique modality designed to expand the market by reaching underserved & unaddressed populations





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

