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): November 11, 2026

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)	**(Zip Code)**

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

(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 2.02 Results of Operations and Financial Condition.

On November 11, 2026, Vivani Medical, Inc. (the "Company") issued a press release titled *"Vivani Medical Reports Third Quarter 2026 Financial Results and Provides Business Update"* which is attached to this Current Report on Form 8-K (this "Current Report") as Exhibit 99.1 and is incorporated by reference herein.

The information contained in this Item 2.02 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by reference in such a filing.

Item 7.01. **Regulation FD Disclosure**

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 as Exhibit 99.2 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, the Company specifically disclaims any obligation to do so.

The information contained in this Item 7.01 and Exhibit 99.2 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 8.01 Other Events.

On November 12, 2026, the Company issued a press release titled *"Vivani Medical Announces Positive Top-Line Results from SLIM-1™, a First in Human Phase 1 Trial of NPM-139 (semaglutide implant) and Wegovy (weekly semaglutide injections) in Obese and Overweight Subjects,"* which is attached to this Current Report as Exhibit 99.3 and is incorporated by reference.

SLIM-1 was a four-week, open-label, active-controlled Phase 1 clinical trial conducted at a single study center in Australia to evaluate the safety, tolerability and pharmacokinetic profile of low-dose NPM-139, the Company's investigational semaglutide implant, in otherwise healthy overweight or obese participants. Ten participants received NPM-139 and ten participants received the starting dose of Wegovy (0.25 mg of semaglutide administered by weekly injection). Changes in body weight were also measured. NPM-139 is a subdermal implant utilizing the Company's proprietary NanoPortal™ technology and is being designed for once- or twice-yearly administration for chronic weight management.

SLIM-1 Top-Line Results

No adverse events were reported as treatment related in the NPM-139 group, compared with treatment-related adverse events in five of ten participants in the Wegovy group, all of which were gastrointestinal. No serious adverse events were reported in either group.

The pharmacokinetic results showed no rapid increases in drug exposure with NPM-139, with maximum semaglutide levels following a single administration measured at approximately 16 days, compared with approximately 2.4 days following the first weekly Wegovy injection. Over the four-week trial, observed weight loss was 0.79% in the NPM-139 group and 0.82% in the Wegovy group.

NPM-139 Development Plans

Based on the top-line results, the Company plans to advance NPM-139 toward a Phase 2 dose-ranging weight maintenance trial, which is anticipated to begin in 2027. The Company also plans to explore the potential for clinical development of NPM-139 in GLP-1-naïve patients based on the tolerability profile observed in SLIM-1.

Forward-Looking Statements

This Current Report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements other than historical fact, and may include statements regarding the potential of NPM-139 for chronic weight management and once- or twice-yearly administration, the Company's plans to advance NPM-139 toward a Phase 2 dose-ranging weight maintenance trial and the anticipated timing thereof, and the potential for clinical development in GLP-1-naïve patients. These statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that may cause results to differ materially from those set forth in the statements. These risks and uncertainties include, among other things, risks relating to the Company's development and commercialization of product candidates, unexpected costs or delays, and changes in anticipated development plans, strategies and objectives. These and other risk factors that could cause actual results to differ materially from those expressed or implied in our forward-looking statements are and will be discussed in the Company's filings with the U.S. Securities and Exchange Commission from time to time, including its most recent annual report on Form 10-K and any subsequently filed quarterly reports on Form 10-Q. These forward-looking statements and such risks, uncertainties and other factors speak only as of the date of this communication. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Vivani Medical Reports Third Quarter 2026 Financial Results and Provides Business Update
99.2	Vivani Medical, Inc. slide presentation dated November 12, 2026.
99.3	Vivani Medical Announces Positive Top-Line Results from SLIM-1™, a First in Human Phase 1 Trial of NPM-139 (semaglutide implant) and Wegovy (weekly semaglutide injections) in Obese and Overweight Subjects
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: November 12, 2026

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

Vivani Medical Reports Third Quarter 2026 Financial Results and Provides Business Update

Top-line results for SLIM-1™, the first-in-human Phase 1 trial of NPM-139, Vivani's miniature, ultra-long-acting semaglutide implant under development for chronic weight management, are anticipated for announcement later this week

Cortigent-ClearOne merger is awaiting final regulatory approvals allowing establishment of Cortigent as a standalone company trading on the Nasdaq under ticker symbol CRGT

ALAMEDA, Calif., November 11, 2026 (GLOBE NEWSWIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), a clinical-stage biopharmaceutical company developing miniature, ultra-long-acting drug implants utilizing its proprietary NanoPortal™ technology, today reported financial results for the third quarter ended September 30, 2026, and provided a business update.

“The third quarter and recent weeks mark a period of strong progress and forward momentum for Vivani” said Adam Mendelsohn, PhD, CEO of the Company. “The top-line SLIM-1 results will be announced this week. We look forward to sharing those results with shareholders, industry peers, and the broader community of physicians and patients seeking less frequent dosing and the promise of potential improvements in convenience, medication adherence, and tolerability associated with GLP-1 therapies on the market and in clinical-stage development."

Dr. Mendelsohn continued: “Roughly half of patients don’t take their medications for chronic diseases as prescribed, and GLP-1 therapies are no exception. With NPM-139, we are designing a novel GLP-1 therapy that a patient could receive once or twice a year during a routine primary care visit. Another key feature afforded by our unique NanoPortal implant technology is the ability to provide an “off-ramp” when discontinuation of therapy is warranted for example when a woman becomes pregnant or there is an aspiration risk during surgery. While there are multiple GLP-1 injectable candidates targeting monthly or quarterly administration under development, none can offer reversibility comparable to our NanoPortal implants. We strongly believe this could be an important consideration for the more than 20% of current GLP-1 users who are women of child-bearing potential.”

Recent Business Highlights

On October 30, 2026, the Company filed an current report on Form 8-K with the U.S. Securities and Exchange Commission to clarify that the expected close of the of the Cortigent merger remains subject to final regulatory approval and is expected to close shortly after approval is received.

On August 6, 2026, Vivani announced full enrollment and successful initial dosing of all participants in its SLIM-1™ Phase 1 trial for NPM-139, a miniature, subdermal semaglutide implant being designed to provide six- to twelve-months of continuous drug delivery utilizing our proprietary NanoPortal™ technology. The trial of 20 GLP-1 naïve participants in Australia includes low-doses of NPM-139 and Wegovy® to assess safety, tolerability, and pharmacokinetics. Changes in weight were measured. Top-Line results from the SLIM-1 trial are anticipated to be announced later this week.

On July 7, 2026, the Company announced the signing of a new agreement with Novo Nordisk, now known as Novo, to evaluate NPM-139, the Company’s semaglutide drug implant. NPM-139 is under development for chronic weight management. There are no exclusivity provisions for NPM-139, or Vivani’s proprietary NanoPortal technology associated with this agreement.

On July 2, 2026, Vivani announced that it has entered into a definitive agreement and plan of merger (the “Agreement”) among its wholly owned subsidiary Cortigent Inc., ClearOne, Inc., a Nasdaq-listed company, and a wholly owned subsidiary of ClearOne (“MergerSub”), pursuant to which Cortigent will become a wholly owned subsidiary of ClearOne upon consummation. In connection with the transaction, ClearOne is pursuing a financing which aims to raise $10 million to $15 million concurrently with the merger’s closing.

Upcoming Anticipated Milestones

Release of top-line data for SLIM-1, the on-going Phase 1 study of low-dose NPM-139, Vivani’s miniature, ultra long-acting semaglutide implant under development for chronic weight management, are anticipated in November 2026.

Preparation, and submission of an Investigational New Drug (“IND”) Application for NPM-139 to support initiation of a proposed Phase 2 dose-ranging study of this semaglutide implant is planned for 2027.

The transition of Cortigent into an independent, publicly traded company shortly after receiving final regulatory approval and completion of all closing and related financing activities.

Third Quarter 2026 Financial Results
***Cash*:** As of September 30, 2026, Vivani had cash, cash equivalents and restricted cash totaling $15.5 million, compared to $20.8 million as of June 30, 2026.

Research and development expense, net: Research and development expense, net of grants, during the three months ended September 30, 2026 was $5.0 million, compared to $4.5 million during the three months ended September 30, 2025. The increase of $0.5 million, or 11%, was primarily attributable to an increase in the clinical trial related expense from our Biopharm Division.

General and administrative expense, net: General and administrative expense, net of grants, during the three months ended September 30, 2026 was $2.5 million, compared to $2.2 million during the three months ended September 30, 2025. The increase of $0.3 million, or 14%, was primarily attributable to an increase in personnel and related expenses from our Neurostimulation Division and our Biopharm Division.

Other income, net: Other income, net during the three months ended September 30, 2026 was $0.3 million, compared to $0.2 million during the three months ended September 30, 2025. The increase of $0.1 million was primarily attributable to amounts recognized under the Australian R&D Tax Incentive Program and higher interest income earned during the period.

Net loss: For the foregoing reasons, we had a net loss of $7.3 million during the three months ended September 30, 2026 compared to $6.5 million during the three months ended September 30, 2025.

About SLIM-1™ Trial

SLIM-1 is an open-label, active-controlled trial evaluating a low-dose NPM-139 (semaglutide implant) given to 10 participants, and the starting dose of Wegovy (0.25mg/week semaglutide injection) given to 10 participants, over a four-week duration. The trial was designed to evaluate the safety, tolerability and pharmacokinetic profile in overweight or obese participants who are otherwise healthy. Changes in weight were also measured. Top-line results from SLIM-1 are anticipated to be released later this week.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani develops miniature, biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence and improving patient tolerance to their medication. Vivani is developing a portfolio of GLP-1 based implants for metabolic diseases including obesity and type 2 diabetes. These NanoPortal implants are designed for once- or twice-yearly administration to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the numerous challenges associated with the daily or weekly administration of orals and injectables, including tolerability issues and loss of efficacy. 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. For more information, please visit: **www.vivani.com**.

About Cortigent, Inc.

Cortigent, Inc., a wholly owned subsidiary of Vivani, is developing brain implant devices to help patients recover critical body functions. Its patent-protected precision neurostimulation technology platform leverages neuroscience and proprietary microelectronics to create advanced medical devices. Vivani's predecessor, Second Sight Medical Products, previously marketed Argus® II, the first and only medical device to obtain FDA approval to treat a rare form of blindness. This innovative device has helped hundreds of profoundly blind patients to achieve meaningful visual perception. Cortigent's next generation investigational system, the Orion® cortical stimulation system, has been designed to treat blindness caused by common conditions including glaucoma and diabetic retinopathy. Orion has an FDA Breakthrough Device designation, completed a 6-year Early Feasibility Study in 2025 with promising safety and efficacy results and is covered by an extensive intellectual property estate. Cortigent is also applying its core technology to improving recovery of arm and hand motion in patients with paralysis due to stroke. For more information and patient videos, please visit: **www.cortigent.com**.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. 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 are used in this press release, including statements regarding Vivani's business, products in development, including the therapeutic potential or the planned development thereof, and its technology, strategy, cash position and financial runway, and the closing of the Cortigent merger. 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. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, risks of unexpected costs or delays, and risks and uncertainties associated with the development and commercialization of products and product candidates that may impact or alter anticipated business plans, strategies and objectives. 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. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Vivani's expectations in any forward-looking statement. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties are more fully described in periodic filings with the U.S. Securities and Exchange Commission (the "SEC") including the factors described in Vivani's most recent Quarterly Report on Form 10-Q filed with the SEC on August 13, 2026, as updated by future filings with the SEC. 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 of this press release. 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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VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Balance Sheets (Unaudited)
(In thousands, except per share data)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,591	$ 16,232
R&D tax credit incentive receivable	305	654
Prepaid expenses and other current assets	937	1,012
Total current assets	15,833	17,898
Property and equipment, net	2,763	2,879
Operating lease right-of-use assets, net	15,713	17,230
Restricted cash	892	1,338
Deposits and other assets	109	48
TOTAL ASSETS	$ 35,310	$ 39,393
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		

Accounts payable	$ 1,210	$ 1,032
Accrued expenses	1,361	1,736
Litigation accrual	1,790	1,675
Accrued compensation expense	319	365
Lease liability, current portion	1,905	1,794
Total current liabilities	6,585	6,602
Lease liability, noncurrent portion	15,507	17,061
TOTAL LIABILITIES	22,092	23,663
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, par value $0.0001 per share; 300,000 shares authorized; shares issued and outstanding: 0 and 76,428 at September 30, 2026 and December 31, 2025, respectively	9	8
Additional paid-in capital	182,110	164,225
Accumulated other comprehensive income	32	30
Accumulated deficit	(168,933)	(148,533)
TOTAL STOCKHOLDERS' EQUITY	13,218	15,730
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 35,310	$ 39,393

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Operations (Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development, net of grants	$ 5,021	$ 4,519	$ 13,978	$ 13,496
General and administrative, net of grants	2,511	2,206	7,375	7,250
Total operating expenses	7,532	6,725	21,353	20,746
Loss from operations	(7,532)	(6,725)	(21,353)	(20,746)
Other income, net	282	195	953	770
Net loss	$ (7,250)	$ (6,530)	$ (20,400)	$ (19,976)
Net loss per common share - basic and diluted	$ (0.08)	$ (0.11)	$ (0.24)	$ (0.34)
Weighted average common shares outstanding - basic and diluted	90,119	59,711	86,192	59,399



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 November 12, 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.

Vivani Medical, Inc.

Miniature implants dosed once or twice a year, designed to address the adherence and tolerability barriers that limit GLP-1 therapy today

Our focus: Enhance patient outcomes in $190B projected* GLP-1 market via differentiated route of administration designed to improve patient adherence, tolerability, and convenience.

Platform Technology: NanoPortal™, a proprietary miniature, subdermal implant designed for smooth and steady drug release over 6 months, 12 months, or longer

Lead program: NPM-139 (semaglutide) ultra-long-acting implant for chronic weight management in obese and overweight individuals

Nasdaq: VANI

Phase 1 SLIM-1™ trial completed

- Strong safety and tolerability profile observed for NPM-139
- Encouraging delivery profile
- Encouraging preclinical translation, enabling streamlined development

NPM-139 is designed to:

- Replace weekly or monthly dosing with a once- or twice-yearly implant
- Ensure adherence for the life of the implant
- Improve tolerability

Novo Nordisk NPM-139 evaluation ongoing

Highly specialized **in-house manufacturing** operations

*Morgan Stanley Research published in April 2026 estimates the global GLP-1 market could reach approximately $190 billion by 2035 across obesity and diabetes, with an obesity-only TAM of approximately $150 billion. Current eligible-patient penetration in the U.S. is estimated at approximately 6%; a bull-case projection is approximately $240 billion. https://www.morganstanley.com/insights/articles/glp1-weight-loss-market-may-double-190-billion-2035

NPM-139 is designed to address adherence and tolerability barriers to sustained GLP-1 therapy

A removable, once- or twice-yearly subdermal semaglutide implant for chronic weight management

Real-World Adherence Gaps

Existing GLP-1 Treatments[1]:

>50% of patients regularly miss doses
>50% discontinue by year 1
~75% discontinue by year 2

NPM-139 **One implant** replaces up to 52 weekly injections **Adherence is assured** for 6 or 12 months

GI Intolerability

Existing GLP-1 Treatments:

GI side effects are the leading medical reason patients stop therapy, particularly during dose escalation

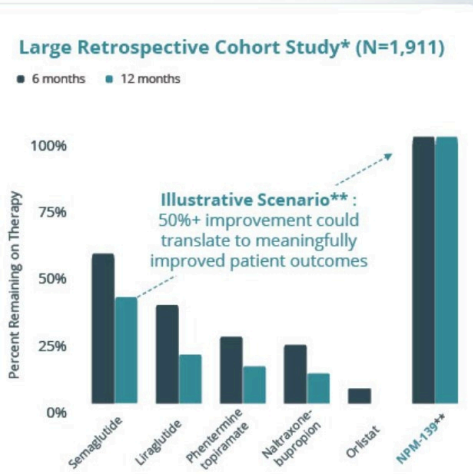
NPM-139 Smooth and steady release is designed to avoid the peak plasma levels that are thought to drive GI events

[1] Gleason, P. P., Urick, 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

Most patients discontinue GLP-1 therapy within one year, limiting long-term benefits

Real-world discontinuation rates for obesity therapies show **the unmet need is significant**.

NPM-139 semaglutide implant is designed to guarantee adherence during the entire once- or twice-yearly dosing interval



** NPM-139 not included in this Large Retrospective Cohort Study, included for illustrative purposes only; assumes full replacement at 6 months

Vivani

* Published in Obesity, December 8, 2023



GI side effects drive substantial levels of medical discontinuation of GLP-1 therapy

Nausea, vomiting and diarrhea are reported by a large share of patients across approved and late-stage GLP-1 therapies

25–44%

Nausea

Reported across approved and late-stage GLP-1 therapies; the most common GI event in the class

8–24%

Vomiting

Most frequent during dose escalation, when plasma levels step up with each titration

9–30%

Diarrhea

With nausea, the top reason for GI-related treatment discontinuation

Tolerability-related dropouts cluster in the dose-escalation phase, when each titration step raises peak plasma levels. The problem is the dose ladder as much as the molecule.

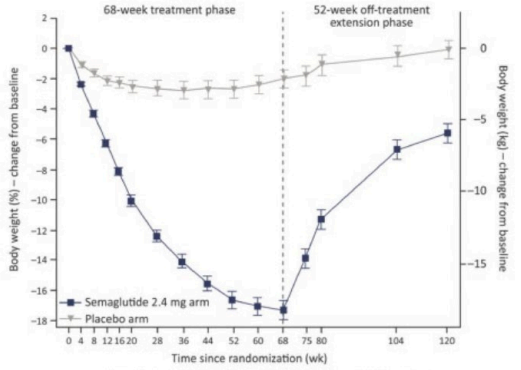
Vivani

Sources: UBS Research, Oct 2026 (GI event prevalence across GLP-1 therapies); Jefferies Research, Oct 2026 (timing of discontinuation relative to dose escalation). Ranges pool multiple agents and trials and describe the class, not any single product label.

GLP-1 (semaglutide) discontinuation leads to rapid hunger-induced weight rebound

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

NPM-139 semaglutide implant is designed to keep patients on therapy by addressing adherence and tolerability barriers



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

[1]Wilding et al., *Diabetes, Obesity and Metabolism*, 2022

Large pharma is investing heavily in extending GLP-1 dosing intervals

Approved GLP-1s are dosed daily or weekly.

Recent investments target monthly and beyond.

Vivani is developing once- or twice-yearly dosing

APPROVED TODAY

- **Wegovy® pill (semaglutide)** Novo Nordisk · oral
- **Wegovy®** Novo Nordisk · injection
- **Foundayo (orforglipron)** Eli Lilly · oral
- **Zepbound® (tirzepatide)** Eli Lilly · injection
- **Saxenda® (liraglutide)** Novo Nordisk · injection

AVAILABLE AS WEEKLY INJECTIONS OR DAILY PILLS

WHERE PHARMA IS INVESTING (SELECT TRANSACTIONS)

- **Pfizer / Metsera** Phase 2 asset at acquisition targeting monthly injectable **~$10B acquisition**
- **Eli Lilly / Camurus** Phase 1b asset targeting monthly semaglutide depot **Up to $870M**
- **Novo Nordisk / Nanexa** Preclinical asset targeting monthly and quarterly dosing **Up to ~$1.3B**

IN-HOUSE PROGRAMS

- **Amgen MariTide** Phase 3 asset targeting monthly and "extended-interval" dosing
- **Viking VK2735** Phase 3 assets targeting biweekly and monthly dosing

VIVANI NANOPORTAL (IN DEVELOPMENT)

NPM-139

Subdermal semaglutide implant designed for

- **Adherence Guaranteed** Throughout the once- or twice-yearly dosing interval
- **Improved Tolerability** SLIM-1 data and NanoPortal technology suggest potential for best-in-class tolerability profile
- **Reversibility** Reversibility if discontinuation is warranted due to pregnancy or aspiration risk in surgery (unlike other ultra-long-acting technologies)

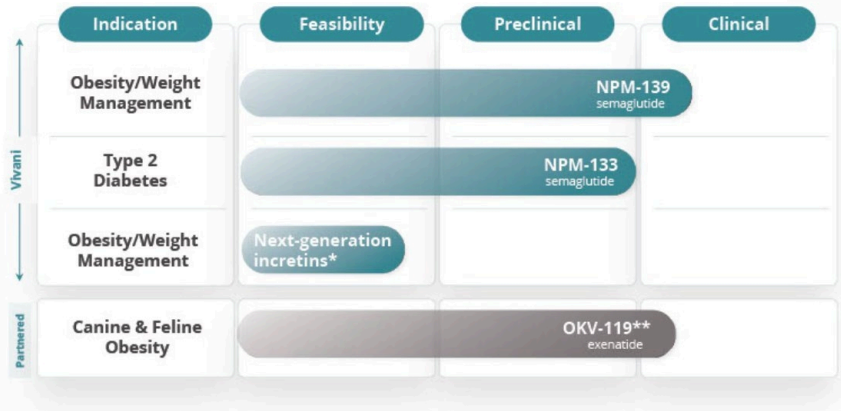
Daily · Weekly · Monthly · Quarterly · Twice-yearly · Once-yearly

Dosing interval → fewer administrations per year

Deal values are headline/up-to amounts including milestones and contingent payments; not all will be paid. ~$12B = Pfizer/Metsera (up to $10B incl. CVR; closed Nov 2025) + Novo Nordisk/Nanexa (up to EUR 1.165B; Sep 2026) + Eli Lilly/Camurus (up to $870M; Jun 2025). MariTide: Phase 3 MARITIME program. VK2735: maintenance study topline Sep 22, 2026. Wegovy® pill approved Dec 2025; Foundayo (orforglipron) approved Apr 2026. NPM-139 is investigational; dosing intervals are development targets. Sources: company announcements.

Company pipeline utilizing NanoPortal platform

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



*This includes a number of next-generation incretins (i.e., more potent and/or multi-agonists), including retatrutide. Early retatrutide implant PK data is featured in this presentation.
**In partnership with Okava Pharmaceuticals, Inc.

NanoPortal: Good things come in small packages

01
GLP-1 implant & applicator



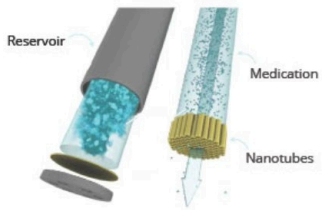
Implant size varies depending upon dose, duration, and potency



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

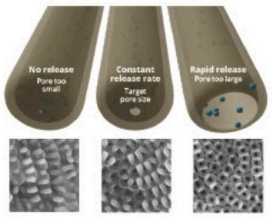
02
NanoPortal device elements

- Biocompatible materials
- Designed to assure adherence
- Long-term delivery

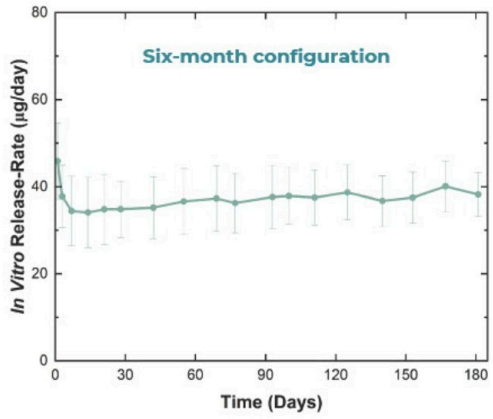


03
NanoPortal technology

- Nanotube pore size is precisely tunable to achieve near-constant release profiles
- Stable and tunable release profile



Proprietary NanoPortal implant technology delivers smooth, near-constant drug release avoiding peaks and troughs associated with orals, injectables and missed dosing

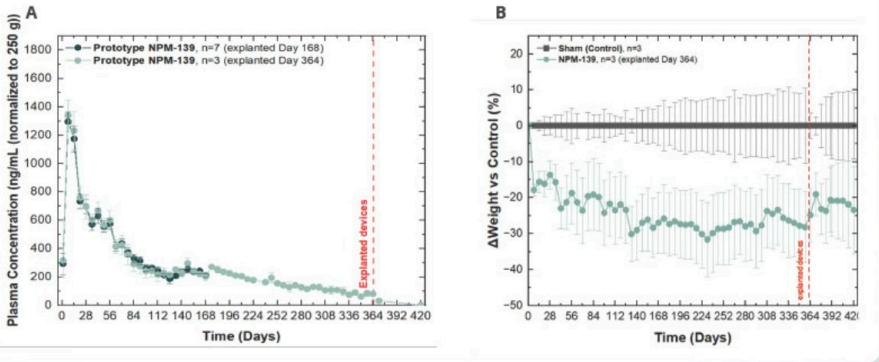


In vitro exenatide release-rate. Day 1 timepoint includes cumulative release over the first day including a separately measured 1st hour of release, which was ~7 µg for the high-dose and ~4 µg for the low-dose. Values are mean ± SD.

*Release-rates include exenatide and related substances.

Vivani

Prototype NPM-139 demonstrates sustained weight loss and delivery for a full year



Prototype NPM-139 (semaglutide implant), 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 ± SE.

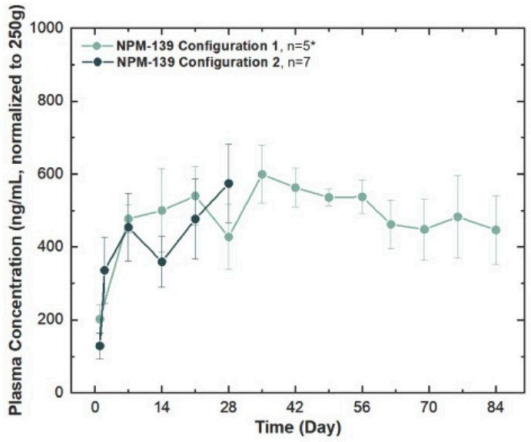
Normalized semaglutide plasma concentrations remain measurable throughout the entire 364-day duration. Implant removal results in immediate decline in plasma levels, as expected.

Vivani

NPM-139 provides steady preclinical pharmacokinetics

***In vivo* pharmacokinetics of NPM-139 (semaglutide implant) configurations in Sprague-Dawley rats.** Values are mean ± SE.

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

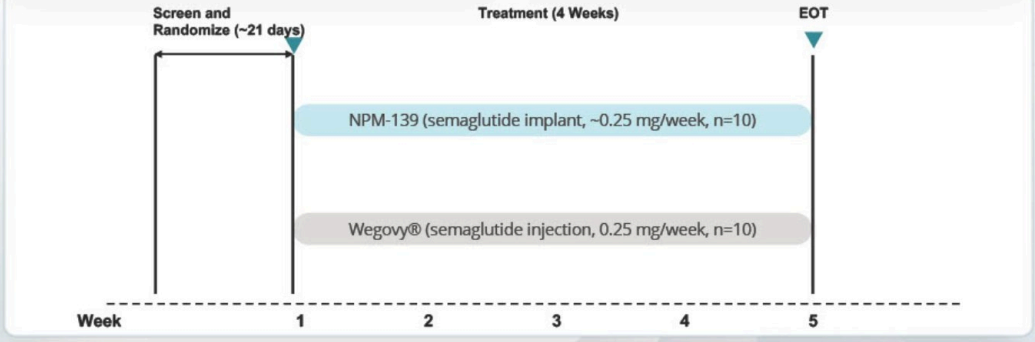


Vivani

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)

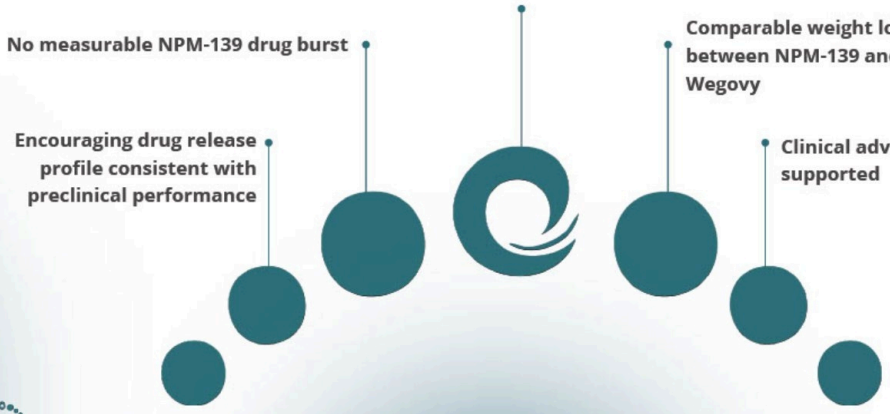


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T2D = Type 2 Diabetes; EOT = End of Treatment

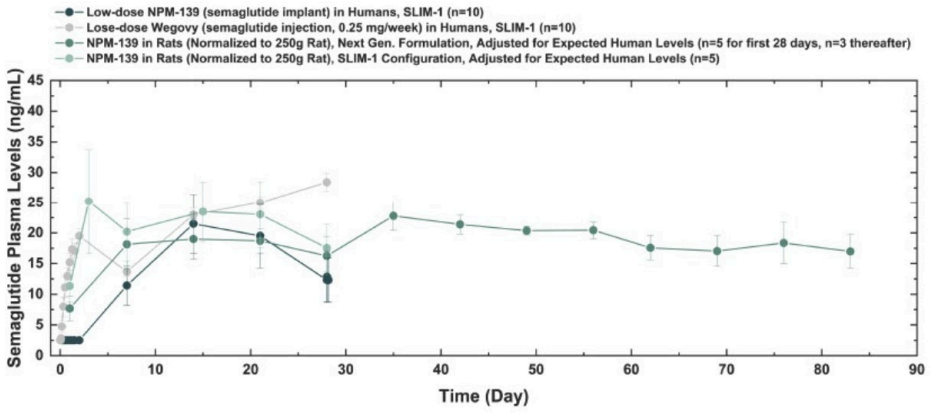
SLIM-1 topline results summary

Positive safety and tolerability
0 of 10 NPM-139 subjects experienced adverse events reported as treatment related
5 of 10 Wegovy subjects experienced gastrointestinal adverse events reported as treatment related



Vivani

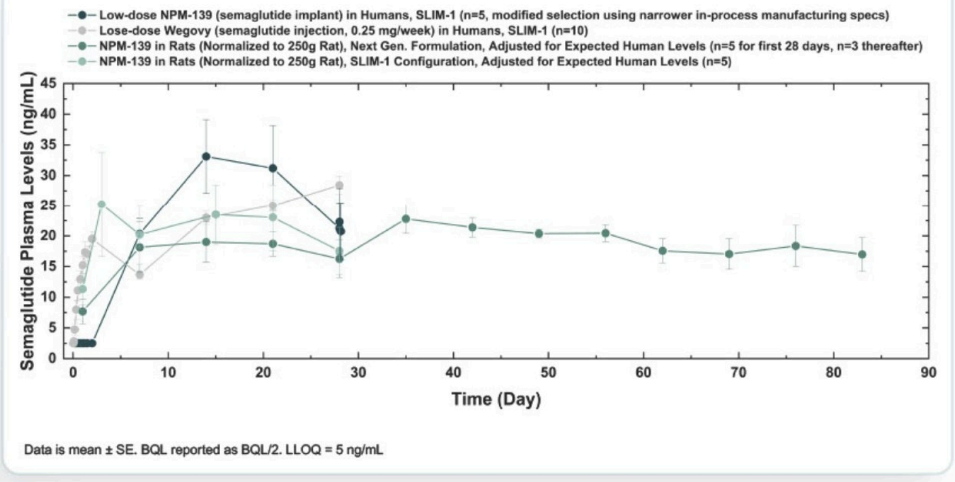
Encouraging Translation of NPM-139 Performance in Rats to Humans in SLIM-1; Full Data Set



Data is mean ± SE. BQL reported as BQL/2. LLOQ = 5 ng/mL

Vivani

Encouraging Translation of NPM-139 Performance in Rats to Humans in SLIM-1; Manufacturing Subgroup



Data is mean ± SE. BQL reported as BQL/2. LLOQ = 5 ng/mL

Strong Gastrointestinal Safety and Tolerability Profile for NPM-139

Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(ITT Analysis Population)

System Organ Class Preferred Term	Semaglutide Implant N=10 n (%)	Semaglutide SC QW N=10 n (%)	Overall N=20 n (%)
Gastrointestinal disorders	1 (10.0)	5 (50.0)	6 (30.0)
Nausea	0	3 (30.0)	3 (15.0)
Abdominal pain	0	2 (20.0)	2 (10.0)
Diarrhoea	1 (10.0)	1 (10.0)	2 (10.0)
Abdominal distension	0	1 (10.0)	1 (5.0)
Constipation	0	1 (10.0)	1 (5.0)

Single treatment-emergent GI AE in the implant group (NPM-139) was reported as not treatment-related

All treatment-emergent GI AEs in the SC group (Wegovy) were reported as treatment-related except for the single case of diarrhoea

0 of 10 NPM-139 subjects experienced gastrointestinal adverse events reported as treatment related

5 of 10 Wegovy subjects experienced at least one gastrointestinal adverse event reported as treatment related

Strong Overall Safety and Tolerability Profile for NPM-139

Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(ITT Analysis Population)

System Organ Class Preferred Term	Semaglutide Implant N=10 n (%)	Semaglutide SC QW N=10 n (%)	Overall N=20 n (%)
Number of participants with at least one TEAE	6 (60.0)	6 (60.0)	12 (60.0)
Gastrointestinal disorders	1 (10.0)	5 (50.0)	6 (30.0)
Nausea	0	3 (30.0)	3 (15.0)
Abdominal pain	0	2 (20.0)	2 (10.0)
Diarrhoea	1 (10.0)	1 (10.0)	2 (10.0)
Abdominal distension	0	1 (10.0)	1 (5.0)
Constipation	0	1 (10.0)	1 (5.0)
Infections and infestations	2 (20.0)	2 (20.0)	4 (20.0)
Upper respiratory tract infection	2 (20.0)	2 (20.0)	4 (20.0)
Immune system disorders	2 (20.0)	0	2 (10.0)
Type IV hypersensitivity reaction	2 (20.0)	0	2 (10.0)
Skin and subcutaneous tissue disorders	2 (20.0)	0	2 (10.0)
Dermatitis contact	2 (20.0)	0	2 (10.0)
Injury, poisoning and procedural complications	0	1 (10.0)	1 (5.0)
Ligament sprain	0	1 (10.0)	1 (5.0)
Nervous system disorders	1 (10.0)	0	1 (5.0)
Headache	1 (10.0)	0	1 (5.0)

Zero adverse events, including GI, in the implant group (NPM-139) were reported as treatment-related

5 subjects in the SC group (Wegovy) experienced at least one GI AE reported as treatment-related

NPM-139 Weight Loss Comparable with Wegovy Control Group

Summary of Body Weight
(ITT Analysis Population)

	Semaglutide Implant N=10			Semaglutide SC QW N=10			Overall N=20		
Visit Statistic	Result (kg)	Change from Baseline (kg)	Percent change from Baseline (%)	Result (kg)	Change from Baseline (kg)	Percent change from Baseline (%)	Result (kg)	Change from Baseline (kg)	Percent change from Baseline (%)
Visit 8 End Of Treatment/Early Termination(Day 29)									
n	10	10	10	10	10	10	20	20	20
Mean	95.21	-0.67	-0.79	90.22	-0.76	-0.82	92.72	-0.71	-0.81
Standard deviation	19.726	1.502	1.699	14.672	0.990	1.172	17.113	1.239	1.420
25th percentile (Q1)	70.90	-1.50	-1.63	81.20	-1.70	-1.85	80.70	-1.60	-1.74
Median	96.60	-1.05	-1.00	85.65	-0.85	-0.84	91.80	-0.90	-0.99
75th percentile (Q3)	114.70	0.30	0.44	95.50	-0.20	-0.21	104.60	0.25	0.33
Minimum	68.0	-3.1	-4.2	77.2	-2.1	-2.5	68.0	-3.1	-4.2
Maximum	117.1	2.1	1.8	127.5	0.8	1.0	127.5	2.1	1.8

NPM-139 subjects (n=10) lost an average of 0.67 kg (0.79%)

Wegovy subjects lost an average of 0.76 kg (0.82%)

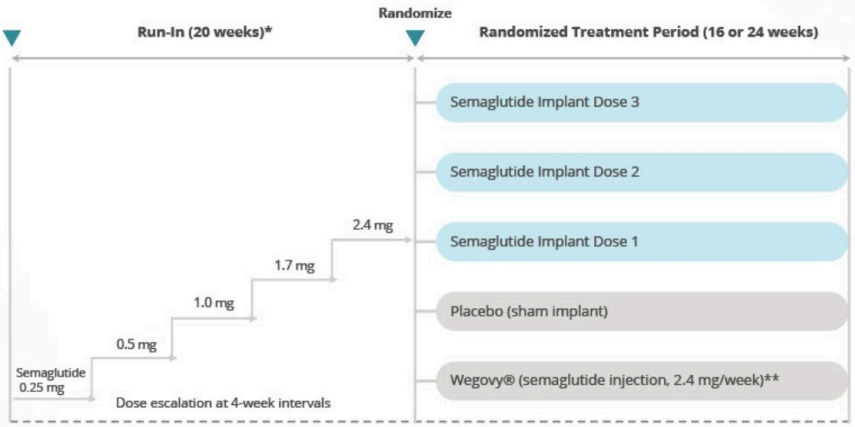
NPM-139 manufacturing subgroup (n=5) subjects lost an average of 1.54 kg (1.78%)

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

Milestone	Status
Reported preclinical proof of concept 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
Reported SLIM-1™, Phase 1 trial, top-line results	November 2026
Initiation of Phase 2 dose ranging study	**2027 (projected)**

Vivani

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



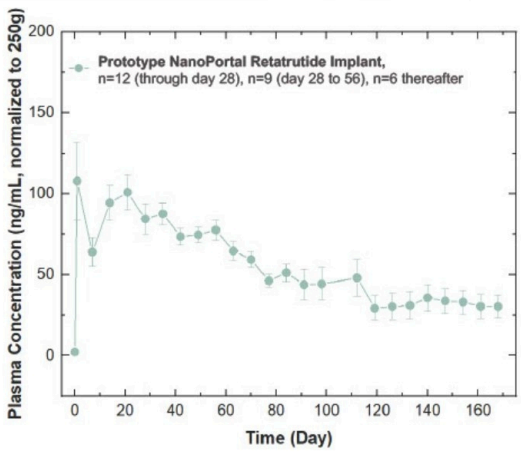
* Individuals who have already lost weight on a GLP-1RA-based therapy may also be included and would forego the run-in

** Unblinded

Vivani

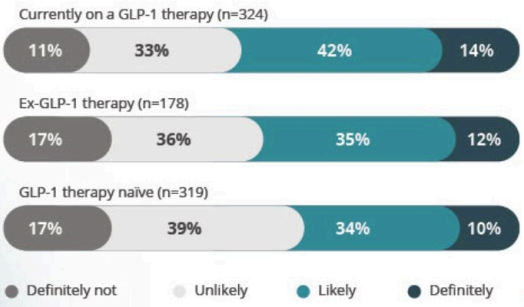
NanoPortal retatrutide implant provides steady preclinical pharmacokinetics

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



Vivani

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



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

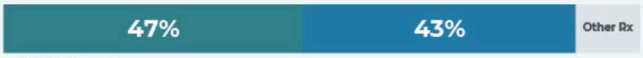
Vivani sponsored qualitative (n=10) market research of diabetes treating primary care physicians, March 2020. ~90% of patients receive treatment in primary care.

Vivani

Contraception analog supports strong adoption potential for an ultra-long-acting GLP-1 implant

THE CONTRACEPTION MARKET: AN ANALOG FOR GLP-1s

Both require chronic dosing, with options spanning daily oral pills and long-acting implants. Among U.S. women ages 15–49 using a prescription contraceptive drug or device:



Denominator: 18.1M

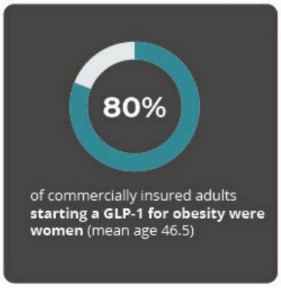
- Oral contraceptive pills — **~8.5M women**
- Long-acting reversible (IUDs, implants) — **~7.9M women**

SUBDERMAL IMPLANT: NEXPLANON®



annual global sales of Nexplanon (etonogestrel implant), FY2024–FY2025

A single long-acting implant has built a near-$1B franchise, demonstrating the commercial potential of subdermal delivery for chronic therapy.



of commercially insured adults **starting a GLP-1 for obesity were women** (mean age 46.5)

Prescription contraceptive drugs or devices: pill, IUD, implant, injectable, ring and patch; excludes sterilization, condoms, withdrawal and fertility-awareness methods. Women using more than one method are classified by the most effective method. The above are estimates. Percentages may not sum due to rounding. Sources: Vivani analysis of 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; August 2025. Organon, Q4 and Full Year 2025 earnings release, February 12, 2026 (Nexplanon/Implanon NXT global sales). "80%" estimate from JAMA Netw Open . 2026 Mar 10;9(3).

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 Eiger 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 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 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. Better outcomes.

- Only GLP-1 implant in development for obesity, chronic weight management, and type 2 diabetes
- Significant improvements in adherence, tolerability and convenience expected to address primary GLP-1 market challenges today and in the future
- Unique opportunity aligning significant potential benefits for patients, prescribers, payors, and investors



Vivani
Nasdaq: VANI



Thank You

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Donald Dwyer, Chief Business Officer
info@vivani.com

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

www.vivani.com

Vivani Medical Announces Positive Top-Line Results from SLIM-1™, a First in Human Phase 1 Trial of NPM-139 (semaglutide implant) and Wegovy (weekly semaglutide injections) in Obese and Overweight Subjects

Strong NPM-139 safety and tolerability profile:

-0 of 10 NPM-139 subjects experienced adverse events reported as treatment related

-5 of 10 Wegovy subjects (control group) experienced adverse events reported as treatment related (gastrointestinal only, consistent with marketed GLP-1 therapies)

Encouraging NPM-139 semaglutide release profile:

-No NPM-139 rapid drug exposure increases; maximum drug levels from a single administration measured at ~16 days (versus ~2.4 days for the Wegovy control group)

-NPM-139 semaglutide delivery was encouraging and consistent with preclinical performance

-Comparable weight loss was observed between the NPM-139 and Wegovy groups

Clinical advancement supported:

-Vivani will advance NPM-139 towards a Phase 2 dose-ranging weight maintenance trial anticipated to begin in 2027

-Vivani will explore the potential for clinical development of NPM-139 in GLP-1-naïve patients based on the positive SLIM-1 tolerability profile

ALAMEDA, Calif., November 12, 2026 (GLOBE NEWSWIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), a clinical-stage biopharmaceutical company developing miniature, ultra-long-acting drug implants utilizing its proprietary NanoPortal™ technology, today reported positive top-line results from SLIM-1, the Company's recently completed Phase 1 trial of low-dose NPM-139 (semaglutide implant) and a control group of low-dose Wegovy™ (semaglutide injection). NPM-139 is a subdermal implant being designed for once or twice-yearly administration under development for chronic weight management in obese or overweight patients.

"The positive top-line data from our SLIM-1 Phase 1 trial marks a critical milestone for Vivani, demonstrating encouraging clinical translation from preclinical models to humans, an encouraging delivery profile, and a strong tolerability profile," said Adam Mendelsohn, CEO of Vivani Medical. "Real-world data show a staggering level of GLP-1 therapy dropoff. By some estimates, more than 50% of GLP-1 users discontinue their therapy within a single year, with gastrointestinal side effects driving much of this attrition. The long-term health outcomes and related pharmacoeconomic value that have been associated with GLP-1 therapy are only realized when patients remain on treatment for durations significantly longer than one year. The absence of rapid drug exposure increases from the NPM-139 group is both desirable and reassuring because rapid increases in drug concentrations have been associated with tolerability issues with other GLP-1 therapies. The strong NPM-139 safety and tolerability profile in SLIM-1 reinforces our belief that NPM-139 may directly address a major reason for attrition in GLP-1 therapies, while simultaneously improving medication adherence and convenience for patients."

Dr. Mendelsohn continued, "We don't know of any other company that is developing miniature, ultra-long-acting, GLP-1 implants that make possible a once- or twice-yearly administration frequency, with the reversibility speed of a weekly injection. We expect that quick reversibility will be a compelling feature for certain segments of the GLP-1 market who would like an ultra-long-acting option but would need one that offers quick reversibility, including the approximately 23% of GLP-1 users who are women of child-bearing age due to recommendations against continued GLP-1 use during pregnancy."

Vivani Chairman of the Board, Gregg Williams, stated, "I'm very excited about the new top-line SLIM-1 data released today and continue to believe these miniature, ultra-long-acting drug implants have the potential to revolutionize the treatment of chronic diseases including obesity and type 2 diabetes. I remain committed to supporting the development of Vivani's portfolio of innovative drug implants and the ultimate benefits these new therapeutic options may deliver to prescribers and their patients."

About SLIM-1™

SLIM-1 is an open-label, active-controlled clinical trial evaluating a low-dose NPM-139 (semaglutide implant) given to 10 participants, and the starting dose of Wegovy (0.25mg/week semaglutide injection) given to a control group of 10 participants, over a four-week duration. The trial was designed to evaluate the safety, tolerability and pharmacokinetic profile in overweight or obese participants who are otherwise healthy. Changes in weight were also measured.

SLIM-1 was conducted in a single study center in Australia. Implant insertions and removals were brief and successfully completed without any complications. The Wegovy group experienced weight loss of 0.82 percent and the NPM-139 group experienced weight loss of 0.79 percent. No serious adverse events (AEs) were reported in the study.

Vivani continues to support Novo Nordisk's evaluation of NPM-139 and the NanoPortal technology under the non-exclusive agreement announced in July 2026.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani develops miniature, biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence and improving patient tolerance to their medication. Vivani is developing a portfolio of GLP-1 based implants for metabolic diseases including obesity and type 2 diabetes. These NanoPortal implants are designed for once- or twice-yearly administration to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the numerous challenges associated with the daily or weekly administration of orals and injectables, including tolerability issues and loss of efficacy. 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. For more information, please visit: **www.vivani.com**.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. 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 are used in this press release, including statements regarding Vivani's business, products in development, including the safety, tolerability, therapeutic potential or the planned development thereof, and its 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. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, risks of unexpected costs or delays, and risks and uncertainties associated with the development and commercialization of products and product candidates that may impact or alter

anticipated business plans, strategies and objectives. 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. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Vivani's expectations in any forward-looking statement. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties are more fully described in periodic filings with the U.S. Securities and Exchange Commission (the "SEC") including the factors described in Vivani's most recent Quarterly Report on Form 10-Q filed with the SEC on November 12, 2026, as updated by future filings with the SEC. 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 of this press release. 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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