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 13, 2025

Vivani Medical, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36747**	**02-0692322**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1350 S. Loop Road
Alameda, California 94502
(Address of principal executive offices, including zip code)

(415) 506-8462
(Telephone number, including area code, of agent for service)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	VANI	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 13, 2025, Vivani Medical, Inc. (the "Company") issued a press release entitled *"Vivani Medical Provides Business Update and Reports Third Quarter 2025 Financial Results,"* which is attached to this Current Report as Exhibit 99.1.

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 on Form 8-K 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 on Form 8-K, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release issued November 13, 2025.
99.2	Corporate Slides as of November 13, 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: November 13, 2025

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

Vivani Medical Provides Business Update and Reports Third Quarter 2025 Financial Results

Company plans to initiate Phase 1 clinical study of semaglutide implant for chronic weight management in the first half of 2026 and parallel investments in studies to enable rapid initiation of Phase 2 dose-ranging study, pending Phase 1 results and regulatory feedback

3Q 2025 private placement, together with October financings, generated approximately $25.7M in cash and cash commitments to support accelerated development of NPM-139 while securing financial position into 2027

ALAMEDA, Calif., Nov. 13, 2025 (GLOBE NEWSWIRE) – Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), a biopharmaceutical company developing miniaturized, ultra long-acting drug implants, today reported financial results for the third quarter ended September 30, 2025, and provided a business update.

Vivani Chief Executive Officer Adam Mendelsohn, Ph.D., stated, "Vivani achieved significant progress during the third quarter of 2025 including the successful completion of LIBERATE-1, marking the first clinical application of the Company's proprietary platform technology, NanoPortal™. This study paves the way for continued development of our growing pipeline of ultra long-acting miniature drug implants, including NPM-139 and NPM-133, our semaglutide-based implants in development for chronic weight management and treatment of type 2 diabetes, respectively. Our initial focus is on the Phase 1 study, which we anticipate will generate clinical data supporting both semaglutide development programs."

Dr. Mendelsohn added, "Vivani remains the only company developing ultra long-acting miniature GLP-1 implants designed for once- or twice-yearly dosing. Our NanoPortal drug delivery platform is uniquely differentiated from a competitive landscape that includes over 50 injectable and oral candidates in development for chronic weight management by offering both infrequent administration and peace of mind that, if necessary, treatment can be discontinued at any time. NanoPortal GLP-1 implants promise to address two of the main challenges in obesity treatment today that contribute to suboptimal patient outcomes: poor medication adherence and poor tolerability. We are excited to be positioned to initiate clinical development of the semaglutide implant program in the first half of 2026."

Recent Business Highlights

On October 28, 2025, Vivani closed its previously announced best efforts registered direct offering of 6,000,000 shares of its common stock at an offering price of $1.62 per share, which was the closing market price on Friday, October 26, 2025, along with the closing of a concurrent private placement of 3,703,703 shares of its common stock at the same offering price of $1.62 per share purchased by an entity affiliated with Gregg Williams, the Chairman of the Company's board of directors. Gross proceeds from the two transactions were approximately $15.7 million, before deducting fees and offering expenses.

On October 3, 2025, Vivani announced that it will temporarily withdraw the previously announced record date for the planned spin-off of Cortigent, Inc. ("Cortigent"), its wholly owned subsidiary developing brain implant devices with cutting-edge neuromodulation technology, due to circumstances surrounding the current shutdown of the U.S. federal government. Vivani expects to establish a new record date shortly after the U.S. Securities and Exchange Commission ("SEC") resumes normal operations. This followed Vivani's earlier announcement on September 17, 2025, indicating that its board of directors had set the record date for the approved spin-off of Cortigent.

On September 4, 2025, Vivani announced plans to initiate a Phase 1 clinical study in the NPM-139 semaglutide implant program in the first half of 2026, pending regulatory clearance. The Company is also preparing to initiate a Phase 2 clinical study of NPM-139 pending enabling results from the Phase 1 study and regulatory feedback. The NPM-139 clinical program will evaluate the Company's investigational semaglutide implant for chronic weight management in patients who are either obese or overweight with a related comorbidity.

On August 11, 2025, Vivani entered into a share purchase agreement to issue and sell an aggregate of 7,936,507 shares of common stock, priced at $1.26 per share, the closing market price on August 11, 2025, in a private placement with two investors including an entity beneficially owned by Gregg Williams. This private sale transaction is expected to result in gross proceeds of approximately $10.0 million and supports the prioritization and accelerated development of NPM-139 into clinical-stage development with initiation anticipated in 2026.

On August 5, 2025, Vivani announced the rapid advancement of NPM-139, a novel semaglutide implant, following data showing 20% weight loss sustained over more than 7 months, from an ongoing preclinical study of NPM-139 and promising results from the LIBERATE-1 Phase 1 clinical study of NPM-115. LIBERATE-1 represented the first-in-human test of the Company's proprietary NanoPortal implant technology.

Upcoming Anticipated Milestones

Vivani anticipates initiating clinical development of a semaglutide implant, NPM-139, in obesity and chronic weight management in 2026.

Vivani anticipates completing the spin-off of Cortigent, a subsidiary of the Company that develops brain implant devices to help patients recover critical body functions, as an independent publicly traded company shortly after the SEC resumes operations.

Third Quarter 2025 Financial Results

Cash balance: As of September 30, 2025, Vivani had cash, cash equivalents and restricted cash totaling $4.0 million, compared to $19.7 million as of December 31, 2024. The decrease of $15.7 million is primarily attributed to a net loss of $20.0 million, partially offset by a $0.9 million net change to operating assets and liabilities, and non-cash items totaling $1.5 million for depreciation and amortization of property and equipment, stock-based compensation and lease expenses. Including three equity purchase agreements entered into in March 2025, May 2025 and August 2025, an additional $18.6 million of committed capital will be contributed through July 2026.

Research and development expense: Research and development expense during the three months ended September 30, 2025 was $4.5 million, compared to $4.2 million during the three months ended September 30, 2024. The increase of $0.3 million was primarily attributable to increased research and development expenses.

General and administrative expense: General and administrative expense during the three months ended September 30, 2025 was $2.2 million, compared to $2.1 million during the three months ended September 30, 2024. The increase of $0.1 million was primarily attributable to increased professional services.

Other income, net: Other income, net during the three months ended September 30, 2025 was $0.2 million, compared to $0.3 million during the three months ended September 30, 2024. The decrease of $0.1 million was due to lower interest income.

Net Loss: The net loss during the three months ended September 30, 2025 was $6.5 million, compared to $6.0 million during the three months ended September 30, 2024. The increase in net loss of $0.5 million was primarily attributable to an increase in operating expenses of $0.4 million.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani develops biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence and 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. The Company is also considering another semaglutide implant for the treatment of type 2 diabetes. These NanoPortal implants are designed 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.

About Cortigent, Inc.

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

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the 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 thereof, the planned development thereof, the completion of the LIBERATE-1 trial and reporting of trial results, Vivani's emerging development plans for its product candidates, Vivani's plans with respect to Cortigent 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 related to the development and commercialization of Vivani's products; delays and changes in the development of Vivani's products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct Vivani's development activities, including Vivani's ability to commence clinical development of Vivani's product candidates or successful completion of ongoing clinical trials for product candidates; risks related to the initiation, enrollment and conduct of Vivani's planned clinical trials and the results therefrom; Vivani's history of losses and Vivani's ability to access additional capital or otherwise fund Vivani's business; risks that the Cortigent spin-off will not be completed in a timely manner or at all; risks of failure to satisfy any conditions to the spin-off; risks of failure of the spin-off to qualify for non-recognition of gain or loss for U.S. federal income tax purposes; uncertainty of whether the anticipated benefits of the spin-off can be achieved; 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. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, risks related to market conditions and the ability of Cortigent to complete its spin-off, Cortigent's history of losses and its ability to access additional capital or otherwise fund its business and advance its product candidates and pre-clinical programs. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. There may be additional risks that the Company or Cortigent consider immaterial, or which are unknown. A further list and description of risks and uncertainties can be found in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 31, 2025, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by Vivani in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of added information, future developments or otherwise, except as required by law.

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VIVANI MEDICAL, INC.
AND SUBSIDIARIES

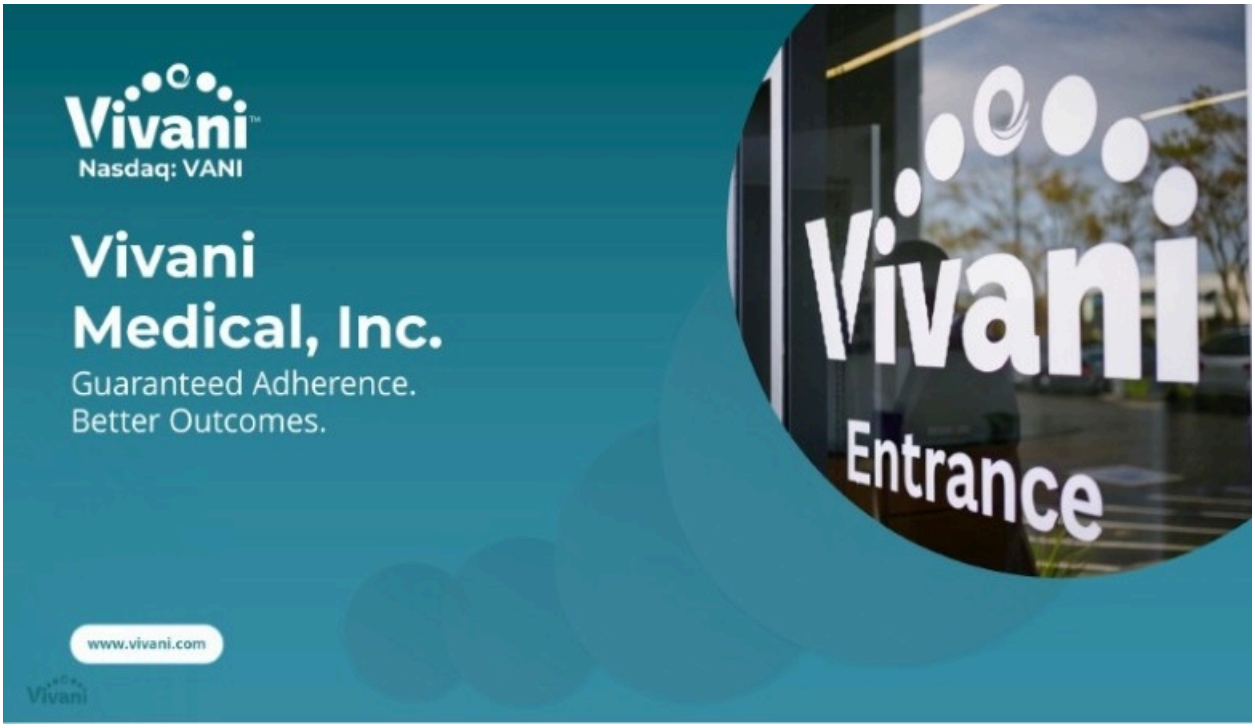
Condensed Consolidated Balance Sheets (unaudited)
(in thousands, except per share data)

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,628	$ 18,352
R&D tax credit incentive receivable	664	253
Prepaid expenses and other current assets	883	1,837
Total current assets	4,175	20,442
Property and equipment, net	2,726	1,693
Operating lease right-of-use assets, net	16,784	17,957
Restricted cash	1,338	1,338
Other assets	23	131
Total assets	$ 25,046	$ 41,561
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,434	$ 817
Accrued expenses	1,978	1,803
Litigation accrual	1,675	1,675
Accrued compensation expense	357	343
Current operating lease liabilities	1,386	1,348
Total current liabilities	6,830	5,986
Long-term operating lease liabilities	16,907	17,965
Total liabilities	23,737	23,951
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share; 10,000 shares authorized; none outstanding	-	-
Common stock, par value $0.0001 per share; 300,000 shares authorized; shares issued and outstanding: 61,511 and 59,235 at September 30, 2025 and December 31, 2024, respectively	6	6
Additional paid-in capital	143,062	139,480
Accumulated other comprehensive income	141	48
Accumulated deficit	(141,900)	(121,924)
Total stockholders' equity	1,309	17,610
Total liabilities and stockholders' equity	$ 25,046	$ 41,561

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,	
	2025	2024	2025	2024
Operating expenses:				
Research and development, net of grants	$ 4,519	$ 4,203	$ 13,496	$ 11,442
General and administrative, net of grants	2,206	2,106	7,250	6,775
Total operating expenses	6,725	6,309	20,746	18,217
Loss from operations	(6,725)	(6,309)	(20,746)	(18,217)
Other income, net	195	268	770	781
Net loss	$ (6,530)	$ (6,041)	$ (19,976)	$ (17,436)
Net loss per common share - basic and diluted	$ (0.11)	$ (0.11)	$ (0.34)	$ (0.32)
Weighted average common shares outstanding - basic and diluted	59,711	55,247	59,399	54,161


Vivani
Nasdaq: VANI
Vivani
Medical, Inc.
Guaranteed Adherence.
Better Outcomes.
Vivani
Entrance
www.vivani.com
Vivani

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.

FDA-approved GLP-1 injectables

3

FDA-approved GLP-1 orals

0

Clinical-stage injectables or orals for obesity

>50

Clinical-stage subdermal implant

1

Vivani

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

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

Nasdaq: VANI

- ✓ Cash runway through key milestones and into 2027
- ✓ NPM-139 clinical program initiation in 1H 2026
- ✓ Manufacturing & operations in Alameda, CA

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

Vivani

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

Company pipeline utilizing NanoPortal platform

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

*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.

Vivani

Good things come in small packages

01

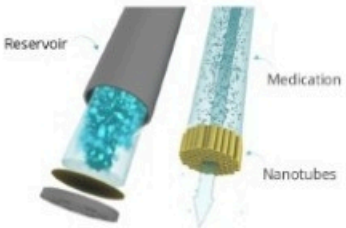
GLP-1 implant & applicator

- ✓ 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

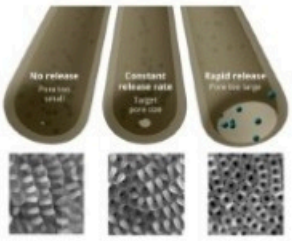
- ✓ Designed to assure adherence
- ✓ Long-term delivery
- ✓ Stable and tunable release profile



03

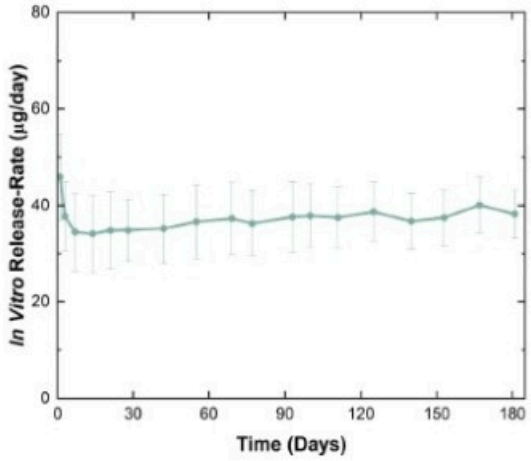
NanoPortal technology

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



Vivani

NanoPortal delivers smooth, near-constant drug release

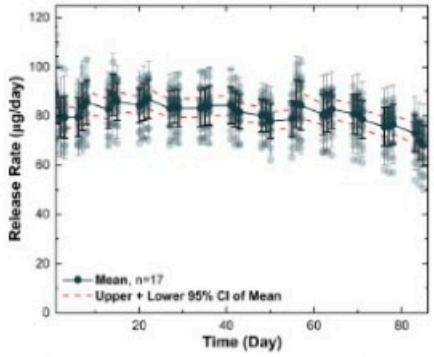


***In vitro* release-rate of exenatide implant (n=6).** Day 1 timepoint includes cumulative release over the first day including a separately measured 1st hour of release, which was ~7 µg for the high-dose and ~4 µg for the low-dose. Values are mean ± SD.

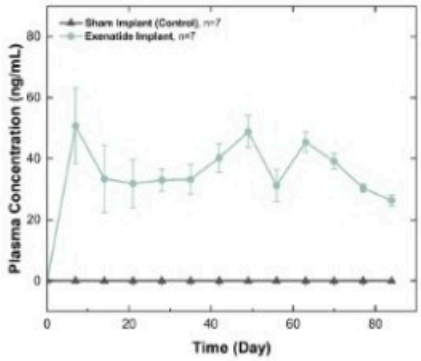
*Release-rates include exenatide and related substances.

Vivani

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.

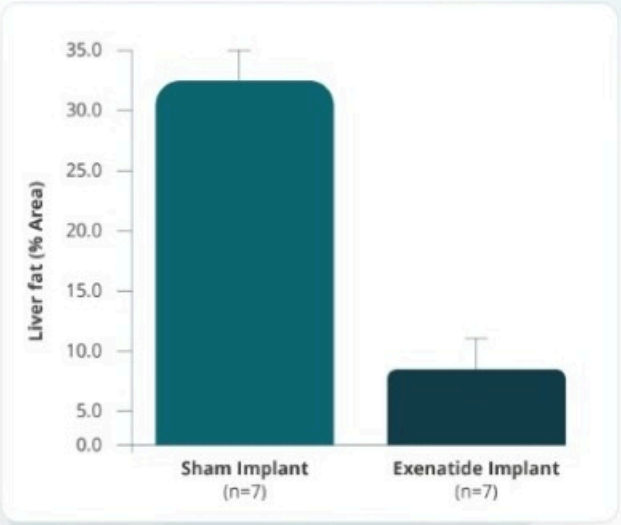


***In vivo* pharmacokinetics of 12-week exenatide implant and sham implant in high fat diet-induced obese mice (n=7 per group).** Values are mean ± SE.

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

Vivani

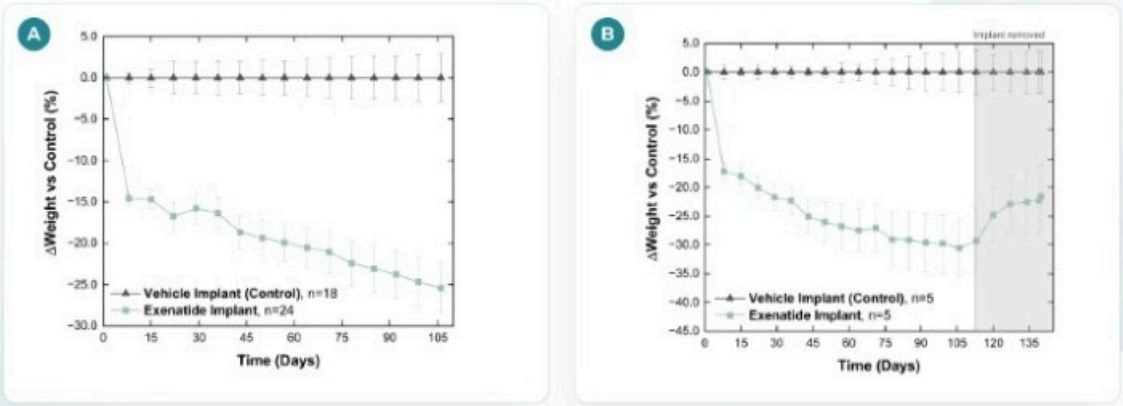
GLP-1 NanoPortal implant reduced liver fat by 82% in preclinical study



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 ± SE.

Vivani

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.

Vivani

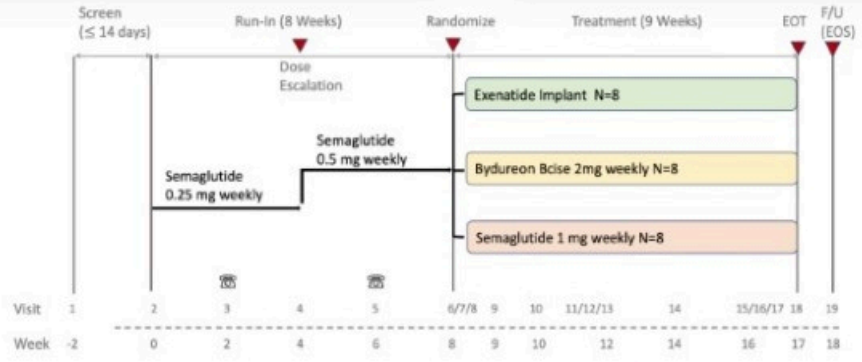
First-in-human GLP-1 NanoPortal clinical trial: LIBERATE-1

Primary Objectives

Safety/tolerability assessment and full pharmacokinetic characterization.

Key Inclusion/Exclusion Criteria

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



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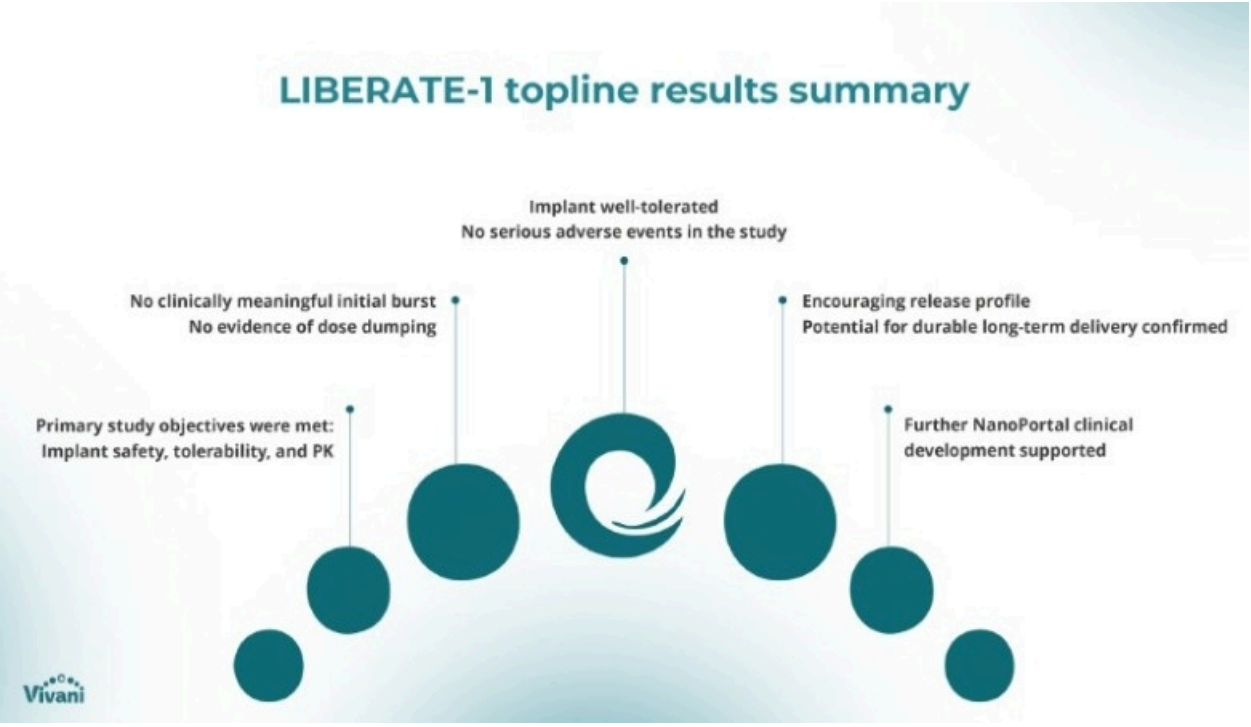
T2D = Type 2 Diabetes; EOT = End of Treatment; EOS = End of Study


LIBERATE-1 topline results summary
Implant well-tolerated
No serious adverse events in the study
No clinically meaningful initial burst
No evidence of dose dumping
Encouraging release profile
Potential for durable long-term delivery confirmed
Primary study objectives were met:
Implant safety, tolerability, and PK
Further NanoPortal clinical
development supported
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Vivani Lead Program: NPM-139
Semaglutide Implant for Chronic Weight Management
Targeting the Rapidly Growing GLP-1 Market
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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 2[2]

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.**

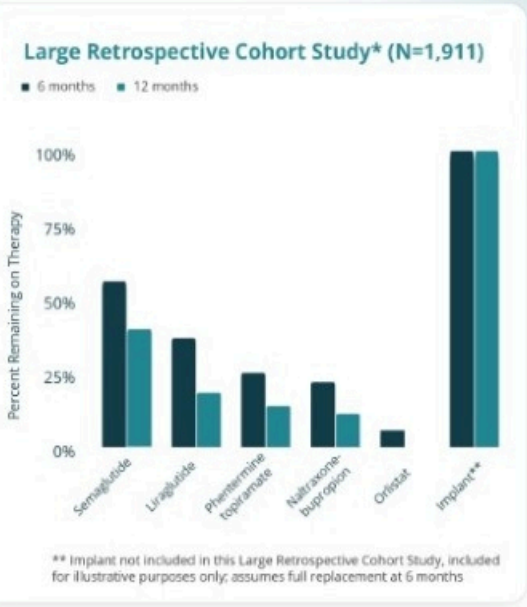
[1] Grand View Research. (2023, November). GLP-1 agonists weight loss drugs market size, share & trends analysis by drugs (Semaglutide (Wegovy), Tirzepatide (Zepbound)), by route of administration, by distribution channel, by region, and segment forecasts, 2025 - 2030. Grand View Research. https://www.grandviewresearch.com/industry-analysis/glp-1-agonists-weight-loss-drugs-market-report

[2] 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

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



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

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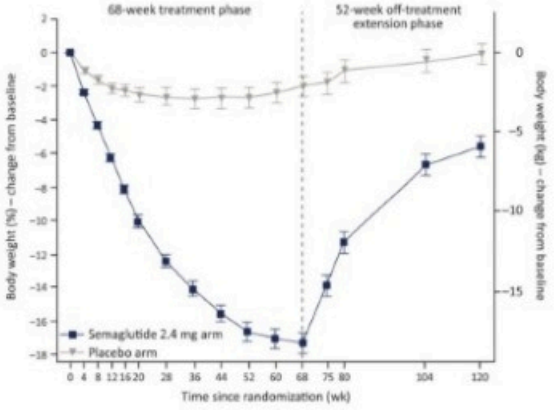
* Published in Obesity, December 8, 2023

Semaglutide discontinuation leads to rapid hunger-induced weight rebound



STEP 1 Extension: Semaglutide Withdrawal

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

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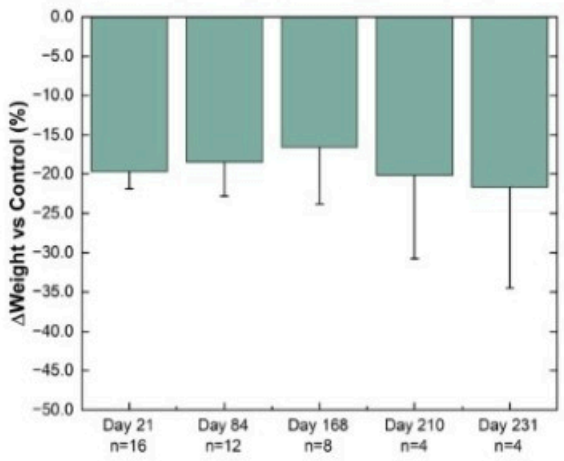
Semaglutide implant successfully delivers durable weight loss in preclinical model for >7 months



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 ± SE.

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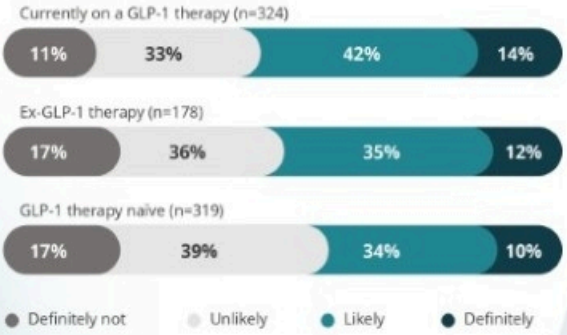
Patient and prescriber research indicates strong adoption potential for a miniature, 6-month GLP-1 implant



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

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

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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

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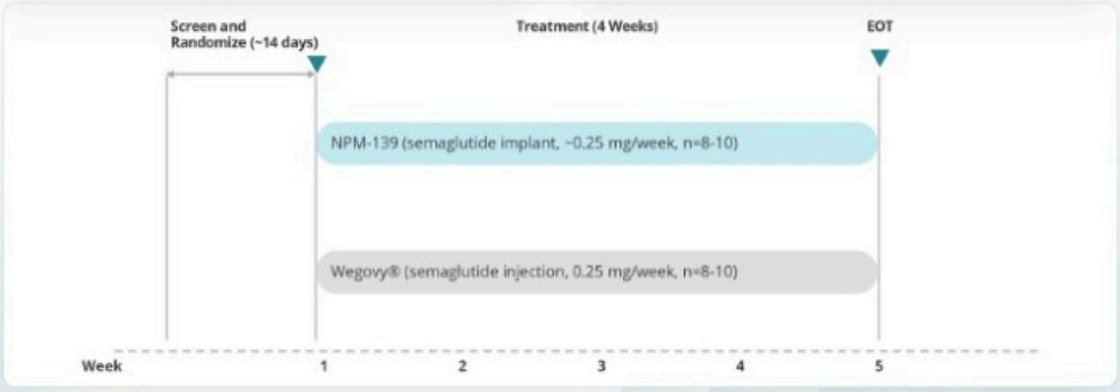

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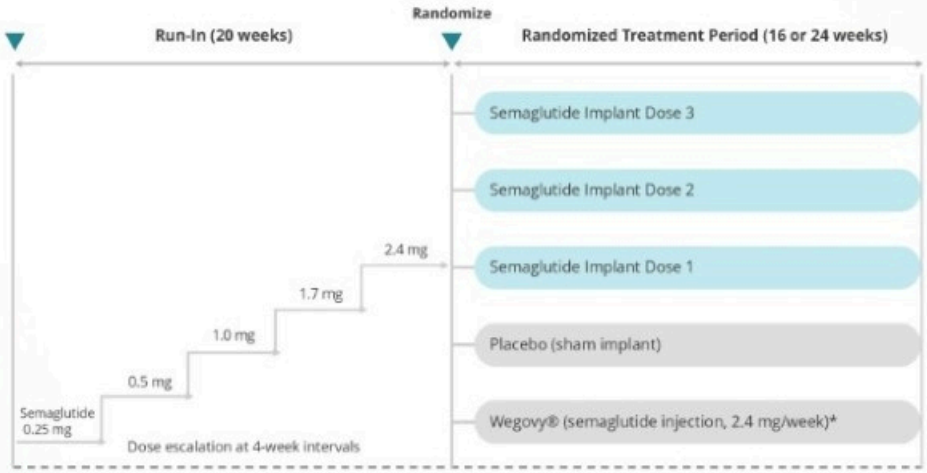
T2D = Type 2 Diabetes; EOT = End of Treatment

Proposed NPM-139 Phase 2 study design



Vivani *unblinded

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

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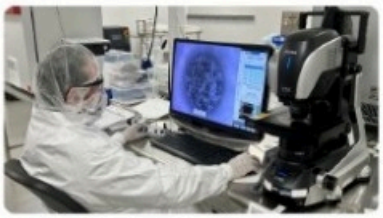
Vivani headquarters and GMP manufacturing facility



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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

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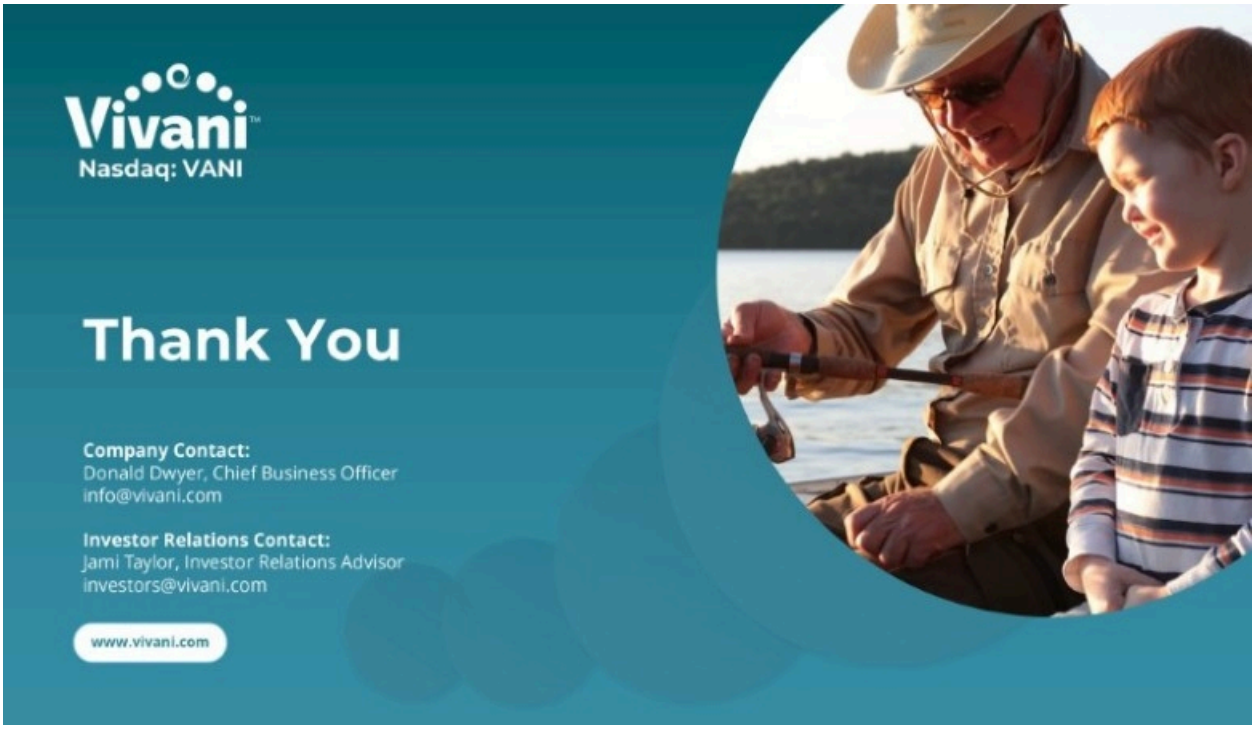
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