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, 2024

VIVANI MEDICAL, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36747**	**02-0692322**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1350 S. Loop Road **Alameda, California** (Address of principal executive offices)	**94502** (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	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, 2024, Vivani Medical, Inc. (the "Company") issued a press release entitled"*Vivani Medical Provides Business Update and Reports Third Quarter 2024 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, 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 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, 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 dated November 13, 2024 entitled *"Vivani Medical Provides Business Update and Reports Third Quarter 2024 Financial Results".*
99.2	Corporate Slides, as of November 13, 2024.
104	The cover page of this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURE

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 13, 2024

By: /s/ Brigid Makes
Brigid Makes
Chief Financial Officer

Vivani Medical Provides Business Update Including $5M Equity Financing and Reports Third Quarter 2024 Financial Results

Regulatory approval to initiate first-in-human study with a miniature, ultra long-acting GLP-1 (exenatide) implant in obese or overweight individuals in Australia

Miniature, ultra long-acting GLP-1 implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing

Announces $5M equity financing which secures solid financial position into late 2025, supporting projected completion of first-in-human study and data read-out

Alameda, CA -- (BUSINESS WIRE) – November 13, 2024 – Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), a biopharmaceutical company developing miniaturized, long-acting drug implants, today reported financial results for the third quarter ended September 30, 2024, and provided a business update.

Vivani's Chief Executive Officer Adam Mendelsohn, Ph.D., stated, "We made significant progress advancing our proprietary GLP-1 implants for obesity and chronic weight management in the third quarter, and we anticipate the initiation of our first-in-human clinical study, named LIBERATE-1, in the fourth quarter of this year. After choosing to conduct our initial first-in-human study in Australia, in part to take advantage of potentially significant rebates from the Australian government, we were excited to receive the regulatory approvals to initiate LIBERATE-1, as a key element of our NPM-115 clinical program in overweight and obese individuals. Today's $5 million common stock financing announcement puts us in an excellent position to complete LIBERATE-1 and continue development of our pipeline programs in 2025."

Dr. Mendelsohn added, "Our NanoPortal drug delivery technology has the potential to directly address medication non-adherence which is responsible for approximately 125,000 avoidable deaths each year in the US alone, more than caused by breast, colorectal and liver cancer combined. In addition, approximately 50% of patients with chronic diseases, including patients with obesity and type 2 diabetes, do not take their medicine as prescribed in the real world, a statistic which holds for both daily orals as well as weekly injectables. GLP-1 drugs have already improved the health of millions of people with obesity and type 2 diabetes, but the future potential impact of these medicines to improve global health across a variety of new indications is even more remarkable. At Vivani, we are addressing the tremendous opportunity to revolutionize the treatment of chronic diseases, including obesity, with our emerging pipeline of miniature, ultra long-acting drug implants specifically designed to ensure medication adherence with twice-yearly, and potentially once-yearly, administration that will allow patients to achieve the full potential benefits of their medicine."

Recent Business Highlights

In July 2024, the Company announced that it expects to initiate the first clinical study in the NPM-115 program in the fourth quarter of 2024 in Australia, pending regulatory clearance in that country. The NPM-115 clinical program will evaluate the investigational 6-month GLP-1 implant for chronic weight management in patients who are either obese or overweight with a related comorbidity.

In September 2024, the Company announced that the Bellberry Human Research Ethics Committee approved, and the Therapeutic Goods Administration in Australia formally acknowledged a first-in-human clinical trial of the Company's miniature, subdermal GLP-1 (exenatide) implant in obese and overweight subjects.

Also in September 2024, the Company reported that its exenatide implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing. The Company previously announced sham-implant adjusted preclinical weight loss of 20%, which is comparable to the weight loss produced from the semaglutide (active ingredient in Ozempic®/Wegovy®) injection control arm in the same study.

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share. The gross proceeds from this private sale transaction were $5.0 million which secures Vivani's financial position into late 2025 and supports projected completion of the first-in-human study and data read-out.

Upcoming Anticipated Milestones

- Vivani plans to initiate LIBERATE-1, a Phase 1, first-in-human study of a miniature, ultra long-acting GLP-1 (exenatide) implant to investigate the safety, tolerability and full pharmacokinetic profile in obese or overweight subjects. The trial will enroll participants who will be titrated on weekly semaglutide injections for 8 weeks (0.25 mg/week for 4 weeks followed by 0.5 mg/week for 4 weeks) before being randomized to receive a single administration of Vivani's exenatide implant (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. Changes in weight will be measured. Data is projected to be available in 2025.

- Vivani will present at the Innovation in Obesity Therapeutics Summit – West Coast on December 10-12, 2024, in San Diego, CA.

Ozempic® and Wegovy® are registered trademarks of Novo Nordisk A/S.

Third Quarter 2024 Financial Results

Cash balance: As of September 30, 2024, Vivani had cash, cash equivalents and restricted cash totaling $21.0 million, compared to $26.3 million as of June 30, 2024. The decrease of $5.3 million is attributed to a net loss of $6.0 million, a decrease of $0.3 million changes in operating assets and liabilities, partially offset by $0.6 million in non-cash items for depreciation and amortization of property and equipment, stock-based compensation and lease expense, and a net cash of $0.4 million provided by financing activities.

Research and development expense: Research and development expense during the three months ended September 30, 2024 was $4.2 million, compared to $4.4 million during the three months ended September 30, 2023. The decrease of $0.2 million, or 5%, was primarily attributable to staffing reduction in Vivani's neurostimulation business and reduced use of outside services, partially offset by the increase in Alameda site facility expenses.

General and administrative expense: General and administrative expense during the three months ended September 30, 2024 was $2.1 million, compared to $2.7 million during the three months ended September 30, 2023. The decrease of $0.6 million, or 22%, was attributable to staffing reduction in Vivani's neurostimulation business along with reduced outside legal and other professional services.

Other income, net: Other income, net during the three months ended September 30, 2024 was $0.3 million, compared to $0.4 million during the three months ended September 30, 2023. The change was not significant.

Net Loss: The net loss during the three months ended September 30, 2024 was $6.0 million, compared to $6.8 million during the three months ended September 30, 2023. The decrease in net loss of $0.8 million was primarily attributable to a decrease in operating expenses of $0.8 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 potentially to improve patient tolerance to their medication. Vivani's lead program, NPM-115, utilizes a miniature, six-month, subdermal, GLP-1 (exenatide) implant under development for chronic weight management in obese or overweight individuals. Vivani's emerging pipeline also includes the NPM-139 (semaglutide implant) which is also under development for chronic weight management in obese and overweight individuals. The semaglutide implant has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's type 2 diabetes development program utilizing a six-month, subdermal exenatide implant. Both the NPM-115 and NPM-119 programs utilize exenatide based products with a higher-dose associated with the NPM-115 program for chronic weight management in obese or overweight patients. These NanoPortal implants are designed to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the challenges associated with the daily or weekly administration of orals and injectables. Medication non-adherence occurs when patients do not take their medication as prescribed. This affects an alarming number of patients, approximately 50%, including those taking daily pills. Medication non-adherence, which contributes to more than $500 billion in annual avoidable healthcare costs and 125,000 potentially preventable deaths annually in the U.S. alone, is a primary and daunting reason obese or overweight patients, and patients taking type 2 diabetes or other chronic disease treatments face significant challenges in achieving positive real-world effectiveness. While the current GLP-1 landscape includes over 50 new molecular entities under clinical stage development, Vivani remains confident that its highly differentiated portfolio of miniature long-acting GLP-1 implants have the potential to provide an attractive therapeutic option for patients, prescribers and payers.

About Cortigent, Inc.

Vivani's wholly owned subsidiary, Cortigent, Inc. ("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 US Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that in this press release, including statements regarding Vivani's business, products in development, including the therapeutic potential thereof, the planned development therefor, the initiation of the LIBERATE-1 trial and reporting of trial results, Vivani's emerging development plans for NPM-115, NPM-139, or Vivani's plans with respect to Cortigent and its proposed initial public offering, 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. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, risks related to the development and commercialization of Vivani's products, including NPM-115 and NPM-119; delays and changes in the development of Vivani's products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct Vivani's development activities, including Vivani's ability to commence clinical development of NPM-119; 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; market conditions and the ability of Cortigent to complete its initial public offering. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties can be found in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission filed on March 26, 2024, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by Vivani in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of added information, future developments or otherwise, except as required by law.

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VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,646	$ 20,654
Prepaid expenses and other current assets	1,753	2,408
Total current assets	21,399	23,062
Property and equipment, net	1,644	1,729
Right-of-use assets	18,383	19,616
Restricted cash	1,338	1,338
Other assets	132	52
Total assets	$ 42,896	$ 45,797
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 815	$ 542
Accrued expenses	2,024	1,727
Litigation accrual	1,675	1,675
Accrued compensation expense	371	396
Current operating lease liabilities	1,385	1,383
Total current liabilities	6,270	5,723
Long-term operating lease liabilities	18,294	19,313
Total liabilities	24,564	25,036
Commitments and contingencies (Note 12)		
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:55,266 and 51,031 at September 30, 2024 and December 31, 2023, respectively	6	5
Additional paid-in capital	134,108	119,054
Accumulated other comprehensive income	92	140
Accumulated deficit	(115,874)	(98,438)
Total stockholders' equity	18,332	20,761
Total liabilities and stockholders' equity	$ 42,896	$ 45,797

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development, net of grants	$ 4,203	$ 4,441	$ 11,442	$ 12,260
General and administrative, net of grants	2,106	2,703	6,775	8,488
Total operating expenses	6,309	7,144	18,217	20,748
Loss from operations	(6,309)	(7,144)	(18,217)	(20,748)
Other income, net	268	362	781	1,122
Net loss	$ (6,041)	$ (6,782)	$ (17,436)	$ (19,626)
Net loss per common share - basic and diluted	$ (0.11)	$ (0.13)	$ (0.32)	$ (0.39)
Weighted average common shares outstanding - basic and diluted	55,247	50,837	54,161	50,757

Nasdaq: VANI
www.vivani.com

Vivani Medical, Inc.

Guaranteed Adherence. Better Outcomes.

November 2024

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 complete any required pre-clinical activities for NPM-115, NPM-119, or otherwise commence our planned clinical trials for these 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, 2024, and our subsequent filings with the SEC. 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 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

Brigid A. Makes, MBA – Chief Financial Officer

- Former Sr. VP and CFO Miramar Labs
- Former Sr. VP and CFO AGA Medical
- Former CFO Nektar Therapeutics, OraVax and Haemonetics
- Current Board director: Quantum-Si and Elutia, Inc.
- Involved in/Directed 2 IPOs, 2 reverse mergers and 1 SPAC

Vivani Medical, Inc.

1. An innovative, biopharmaceutical company developing a portfolio of ultra long-acting, miniature, drug implants to treat chronic diseases. NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability.

2. Lead program NPM-115 utilizes a miniature, six-month, GLP-1 (high-dose exenatide) implant under development for chronic weight management in obese or overweight patients.

3. Pipeline includes IND-cleared NPM-119 utilizes a miniature, six-month, GLP-1 (exenatide) implant under development for type 2 diabetes and NPM-139 (semaglutide implant), under development for chronic weight management with the potential benefit of once-yearly dosing.

4. Vivani is well-positioned to advance NPM-115 and its pipeline towards potentially transformational milestones in 2024 and 2025.

Company Pipeline

If Approved, Vivani Products will Compete in Markets with Large Potential

* Estimated Market Sizes where Vivani products would compete, if approved. Does not represent future sales or revenue estimates of Vivani pipeline products. Evaluate Pharma's "World Preview 2024: Pharma's Growth Burst July 2024" estimates $130B 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.

Drug Implants
Proprietary Platform Technology

GLP-1 (exenatide) Implant and Applicator

Implant size depicted represents approximate size of dose expected for T2DM indication

Vivani

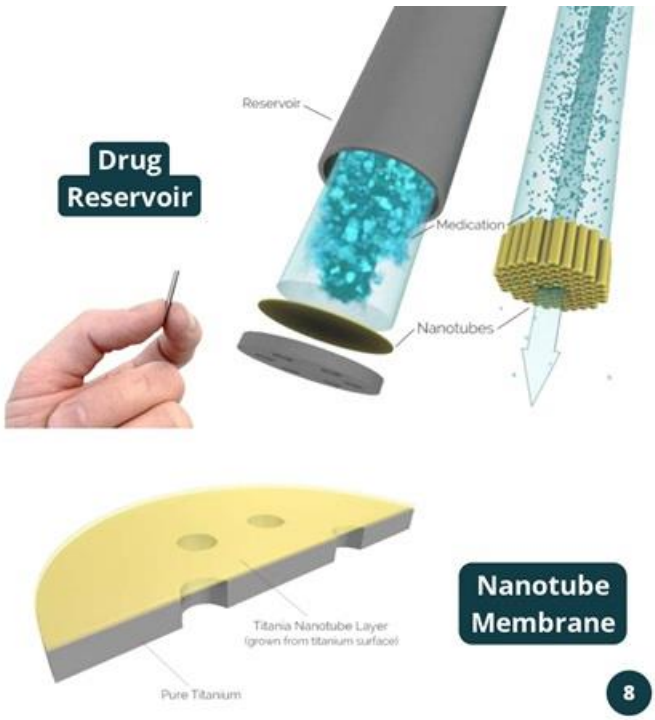
NanoPortal™:

Innovative Delivery Technology

Designed to assure adherence

Minimally-fluctuating and tunable delivery profiles

Potential application with many molecular types

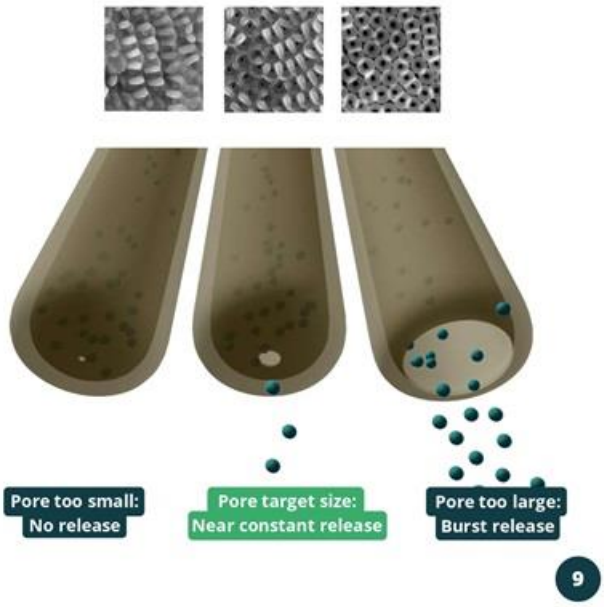


Nanotube Membrane

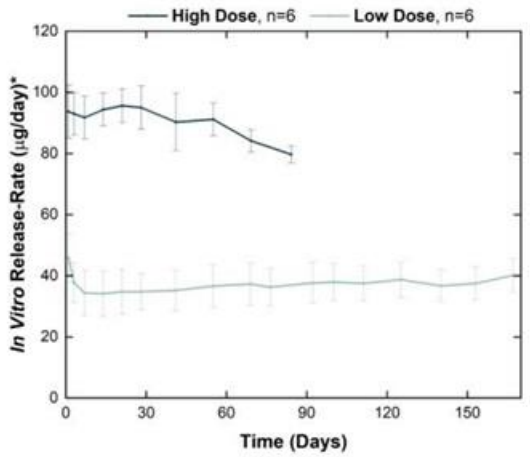
NanoPortal™:

How it Works...

By precisely adjusting nanotubes to molecule size, interactions between drug and nanotube walls can result in desirable release profiles over time, including **near constant release**

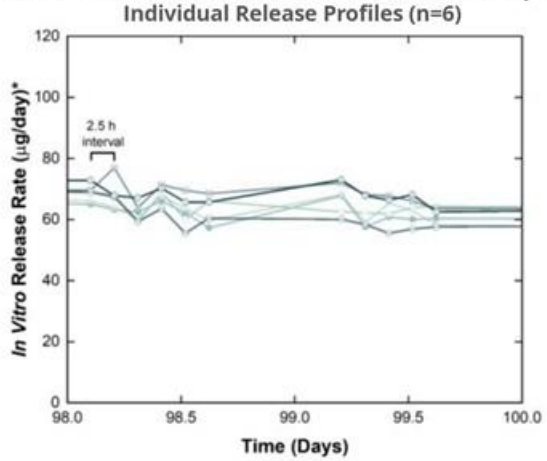


NanoPortal delivers near-constant / minimally-fluctuating drug release



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

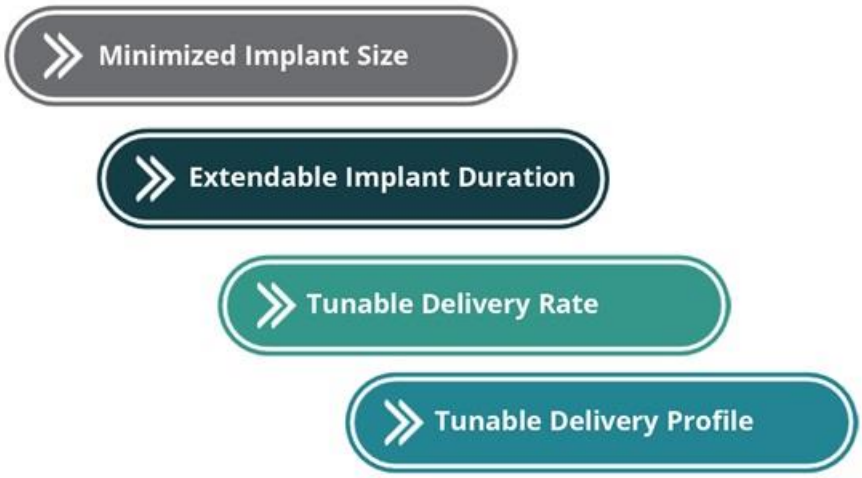
Minimal Fluctuations with 2.5-hour interval sampling
Individual Release Profiles (n=6)



Fluctuations during each 2.5-hour interval are within measurement error

NanoPortal™ is a Platform Technology

Broad Potential Application Can Support Portfolio of New Drug Implants



NanoPortal implant technology designed to avoid earlier device challenges

Osmotic Pump (Intarcia)

- FDA alleges that **daily variations in drug release** may be responsible for **clinical safety signals** which prevented regulatory approval
- **Larger Device** (4mm x 45mm)
- Insertion using **larger 6-gauge needle**

NanoPortal™ (Vivani)

- **Minimally fluctuating drug release** profile observed in pre-clinical studies directly addresses ITCA 650 regulatory challenges
- **Smaller Device** (2.2mm x 21.5mm)*
- Insertion using **smaller 11-gauge needle**

*Approximate expected size of Type 2 Diabetes implant

Vivani Lead Program
NPM-115

High-Dose Exenatide Implant for Chronic Weight Management

Targeting the Rapidly Growing GLP-1 RA Market

Lead Program NPM-115:

Development of 6-Month Exenatide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Chronic Weight Management in Obese or Overweight Patients

- Tremendous unmet medical need in Obesity[1]:
  - 764M people living with obesity
  - 15M (2%) taking an anti-obesity medication
- GLP-1 monotherapy may provide adequate weight loss for the majority of patients[2]
- Preclinical data with NPM-115 has demonstrated similar magnitude of weight loss for exenatide and semaglutide
- NPM-115 target profile may provide an attractive alternative to life-long injections or pills for long-term maintenance of GLP-1 therapy for weight management

[1,2] Novo Nordisk 2023 Annual Report

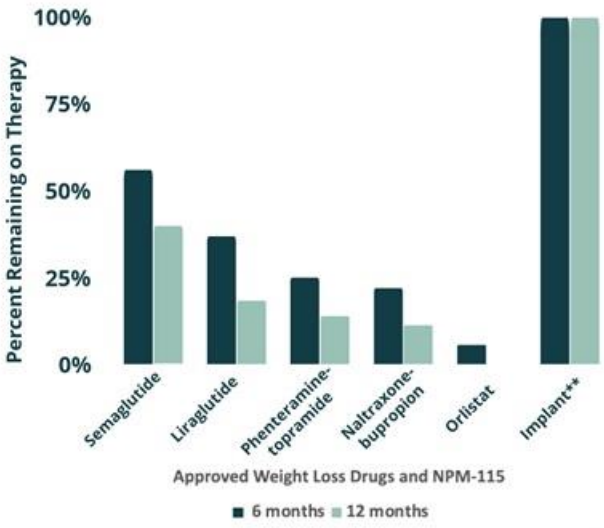
Weight Loss Medicines Associated With Adherence Challenges

Recent retrospective cohort study (n=1,911) reported improved medication persistence with semaglutide of 40% after one year

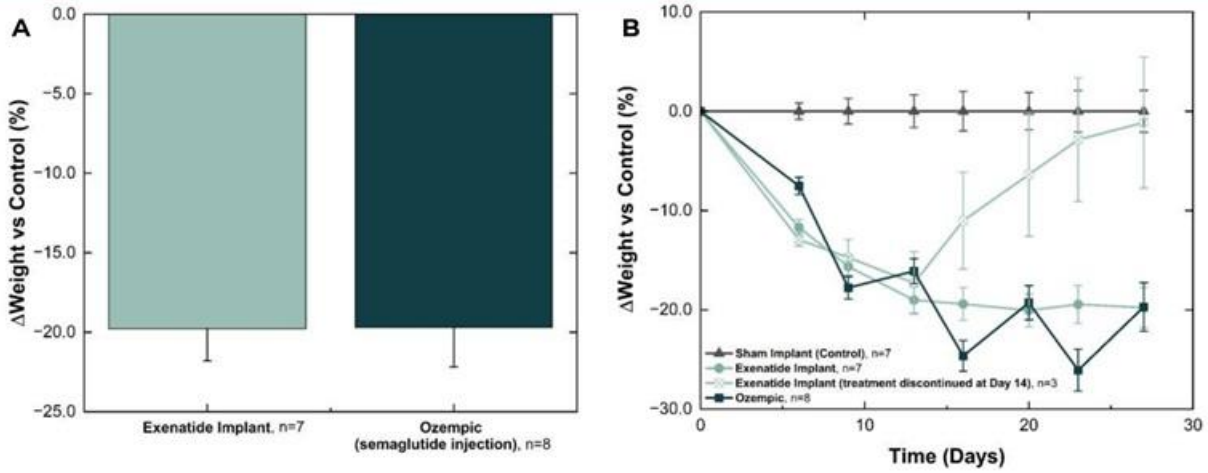
- **The remaining opportunity for an additional 60% improvement in persistence is significant and will translate to improved patient outcomes**
- **NPM-115 (exenatide implant) is designed to guarantee adherence for 6 months / implant**

* Published in Obesity, December 8, 2023
** NPM-115's exenatide implant was not included in the published study, assumes one implant replaced after six months. Currently under development, designed to enable 100% adherence, not approved in any market.

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

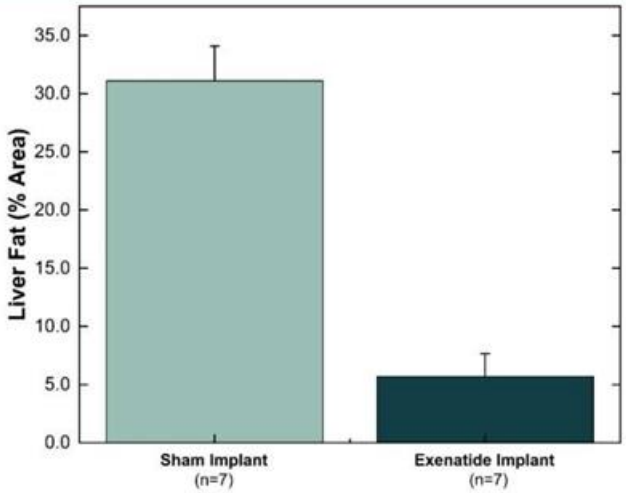


Exenatide implant associated with comparable weight loss to semaglutide in preclinical study



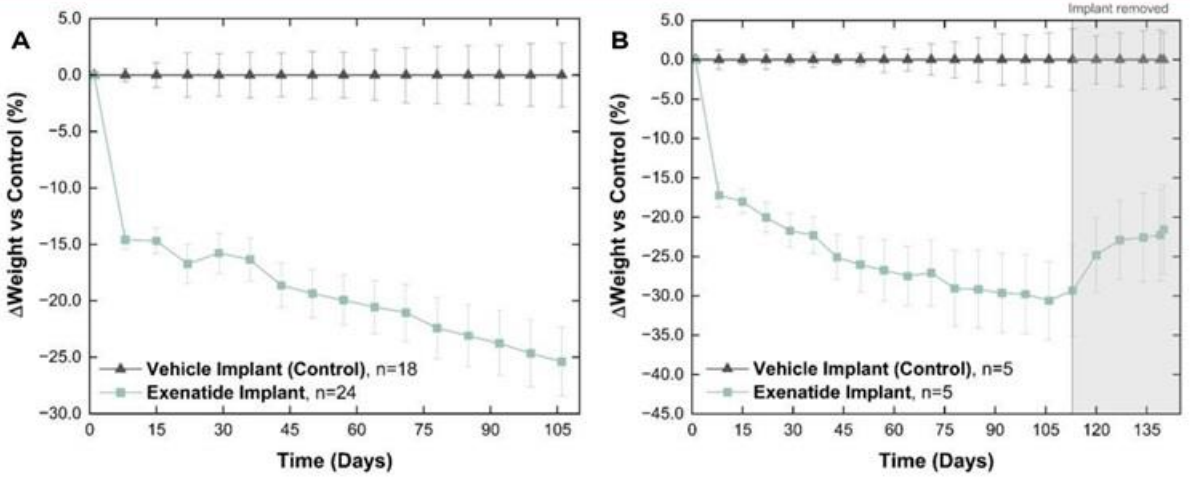
Weight loss in high fat diet-induced obese mice. (A) % weight change from baseline for a single administration of exenatide implant (~530 nmol/kg/day) vs weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant) at 28 days; **(B)** % weight change from baseline over time from a single administration of exenatide implant (~530 nmol/kg/day) vs. weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant). Values are mean ± SE.

Exenatide implant reduces liver fat by 82% in obese mice after 12 weeks



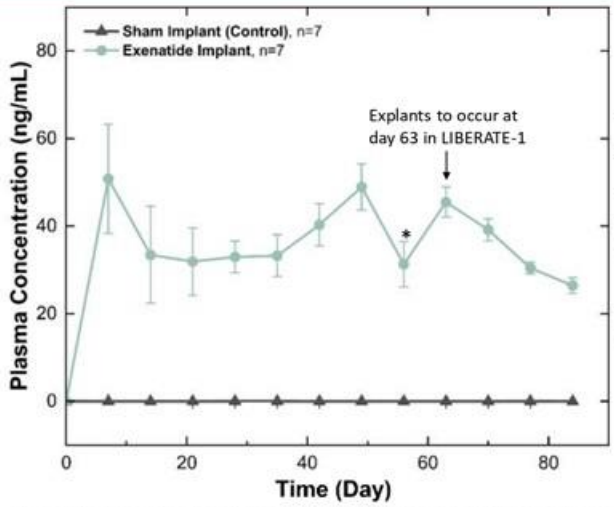
Liver fat reduction in high fat diet-induced obese mice. Liver fat % area for exenatide implant vs sham implant 12 weeks after a single administration. Liver fat % area is calculated using Oil Red O (ORO) staining. Values are mean ± SE. These results are numerically consistent with a similar investigation in which liver fat content was evaluated in high fat diet-induced obese mice that received semaglutide injections.

Exenatide delivered with NanoPortal™ technology is associated with durable body weight effects

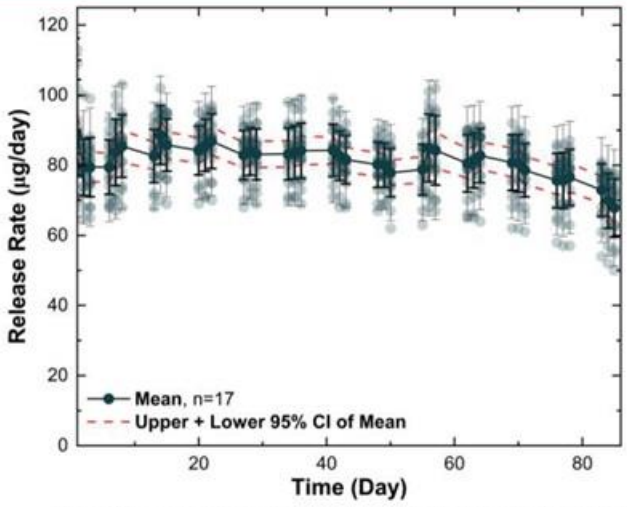


Weight difference from control in healthy Sprague-Dawley Rats. % weight change from baseline for a single administration of exenatide implant in a study associated with NPM-119 (~320 nmol/kg/day) corrected to control (vehicle implant). **(A)** All animals measured through 105 days of treatment; **(B)**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

In vivo and *in vitro* performance of 12-week exenatide implant configuration to be studied in LIBERATE-1

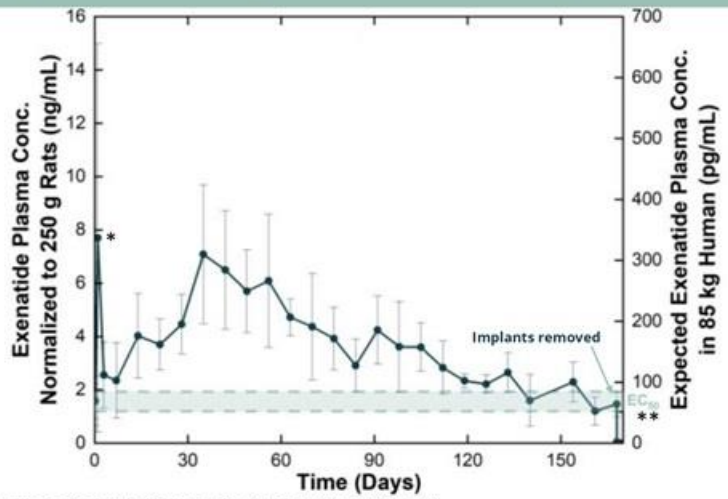


***In vivo* pharmacokinetics of 12-week exenatide implant and sham implant in high fat diet-induced obese mice (n=7 per group).** Values are mean ± SE. *Day 56 values are reported as measured, but a sample handling error at this time point is suspected to have occurred.



***In vitro* release-rate of exenatide implant to be used in LIBERATE-1 (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.

6-Month exenatide implant preclinical proof-of-concept achieved

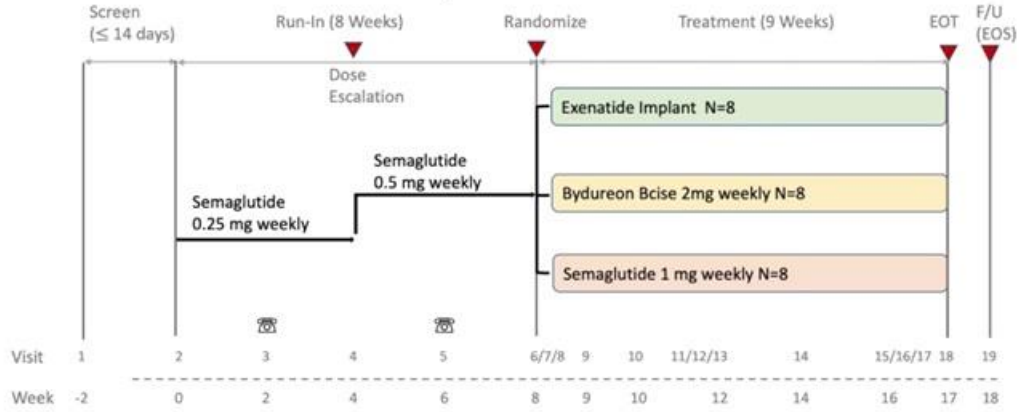


Pharmacokinetics of 6-month exenatide implant in male Sprague-Dawley rats (n=6)
Exenatide antibody-positive animals are not included in this data set. Values are mean ± SD.
*2 of 6 implants are responsible for higher Day 1 exenatide concentrations which is not expected to occur in the configuration to be used in the clinic.
** The estimated exenatide EC50 is 51.4 pg/mL when exenatide antibody titers are < 125 and 84 pg/mL when exenatide antibody titers are >= 125. These exenatide EC50 estimates are consistent with the exenatide EC50 estimate, 83.5 pg/mL, from the FDA Clinical Pharmacology review of BYDUREON

Proposed First-in-Human Trial: LIBERATE-1

Primary Objectives: Safety/tolerability assessment and full pharmacokinetic characterization. Changes in weight will also be assessed.

Key Inclusion/Exclusion Criteria: 18-55 years old; overweight or obese (BMI 27-40)
Otherwise healthy (no T2DM, normal renal function)



NPM-115 Clinical + Regulatory Development Near-Term Plan

Year(s)	Milestone	Status
2023	Announced NPM-115 Program to Evaluate High Dose Exenatide Implant for Chronic Weight Management	November 2023
2024	Reported Positive Weight Loss in Preclinical Study	February 2024
2024	Initiate First-In-Human Study in Obese and Overweight Patients	Expected 4Q2024
2025	Results of LIBERATE-1 available	Expected 2025

November 2023 – Vivani announced the NPM-115 clinical program and initiated development of the exenatide implant for chronic weight management.

February 2024 – Company reported positive preclinical study results demonstrating comparable weight loss between exenatide implant and Ozempic/Wegovy (semaglutide injection) and a strategic shift to focus on obesity and chronic weight management.

June 2024 – Company announced IND clearance for its NPM-119 program to study its exenatide implant in patients with type 2 diabetes. The initial study supporting the NPM-115 obesity program will utilize the same test article as the NPM-119 program (exenatide implant). Study to be conducted in Australia. Study initiation expected in 4Q2024, with study data anticipated in 2025.

NPM-119

Exenatide Implant for Type 2 Diabetes

Targeting the Rapidly Growing GLP-1 RA Market

NPM-119

Development of a 6-Month Exenatide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Type 2 Diabetes

- Significant unmet need in Diabetes[1]:
  - 537M people living with diabetes
  - ~ 15% in good control
- Non-adherence is the primary reason for low, real-world effectiveness[2,3]
- Guaranteed adherence will produce significant healthcare cost savings[4]
- FDA indicated 505(b)(2) streamlined approval pathway may be available

[1] 2023 Novo Nordisk Annual Report
[2] Guo 2016
[2,3] Carls et al., 2017
[4] IMS 2013 Report

Current Drug Adherence Challenge

"Drugs don't work in people that don't take them"

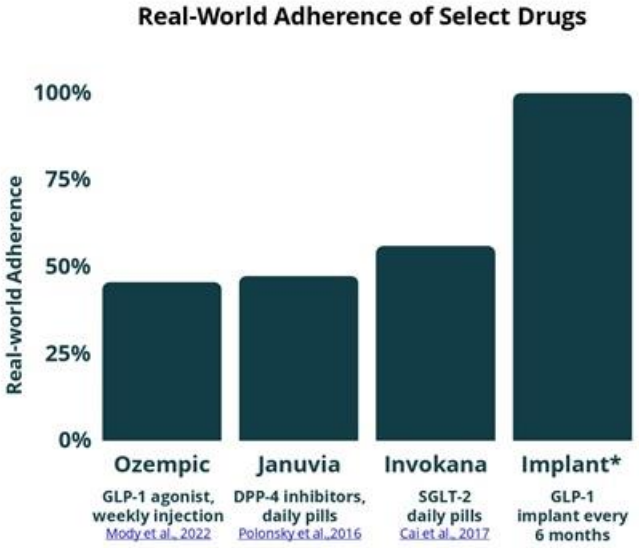
NPM-119* Designed to Enable 100% Adherence through Implant Duration

- Orals and injectables do not guarantee adherence
- Approximately 50% of patients do not meet glycemic targets primarily due to nonadherence

Dual Incentive to Adopt Technology that Improves Adherence

- Pharmaceutical revenue is increased
- Healthcare costs are decreased

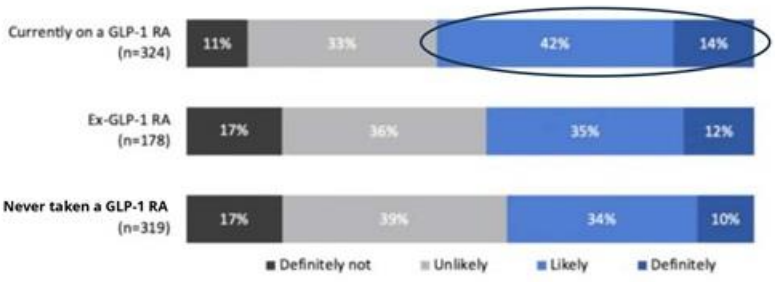
* NPM-119's exenatide implant – under development, designed to enable 100% adherence, not approved in any market



Patient research indicates strong adoption potential for a miniature, 6-month exenatide implant

PWD sentiment towards the ITCA 650 concept is more strongly positive amongst those who are currently on a GLP-1 RA or who have taken one in the past.

Likelihood of getting ITCA 650 exenatide implant if FDA-approved, recommended by HCP, and covered by insurance, by current GLP-1 RA status
(Among people with T2D with A1c>7%)



56% of patients responded "likely" or "definitely" to get an exenatide implant if FDA approved, prescriber recommended, and covered by insurance

Our question, after showing an image of the device and a description* of how it would be used, was:
"Assuming it was approved by the FDA, your doctor suggests it, and insurance coverage is not an issue, how likely would you be to get and use the implant with exenatide?"

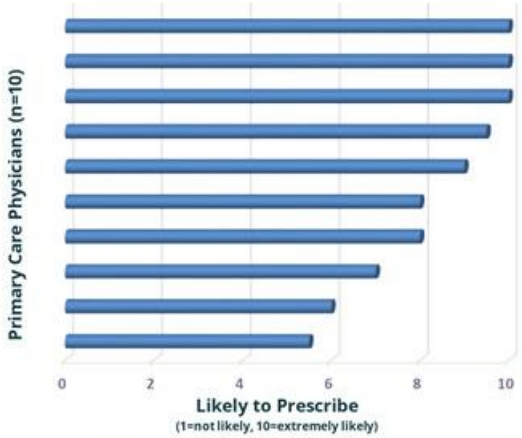
dQ&A

dQ&A insights reported market research during FDA Advisory Board to review ITCA 650 (exenatide implant) on September 21, 2023

Prescriber and Payer research also provide strong support for a miniature, 6-month exenatide implant

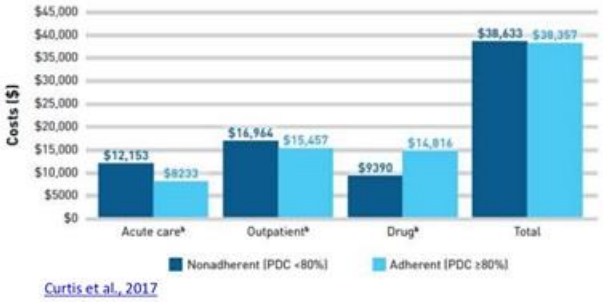
Prescribing Rating, Average 8.3 out of 10

Rating: Overall, using a scale of 1 to 10, where 1 is not at all likely and 10 is extremely likely, how likely are you to prescribe NPM-119?



Adherence = Lower Acute Care & Outpatient Costs

Total: ~$5,500 (annual, per patient)



Curtis et al., 2017

Vivani sponsored qualitative market research, March 2020. ~90% of patients receive treatment in primary care

NPM-119 Clinical + Regulatory Development Near-Term Plan

Year(s)	Milestone	Status
2024	IND cleared	June 2024

June 13, 2024 – Vivani announced that the FDA cleared the NPM-119 IND to enable the evaluation of its exenatide implant in patients with type 2 diabetes.

July 11, 2024 – Vivani reiterated its strategic shift to focus on the obesity applications of its implant technology and expressed its intention for the First In Human study to be in obese and overweight patients as part of the NPM-115 program.

Vivani intends to evaluate its exenatide implant in patients with type 2 diabetes as part of its overall clinical strategy but will begin with obese and overweight patients as part of its NPM-115 program.

Vivani Medical, Inc.
Financial Information

Vivani Medical, Inc.
Q3 2024: Income/(Loss) Statement

Condensed Consolidated Statement of Operations

In Thousands, except Share Data	3 Months Ended Sept. 30, 2024	3 Months Ended Sept. 30, 2023	9 Months Ended Sept. 30, 2024	9 Months Ended Sept. 30, 2023
Operating expenses:				
Research and development, net of grants	4,203	4,441	11,442	12,260
General and administrative	2,106	2,703	6,775	8,488
Total operating expenses	6,309	7,144	18,217	20,748
Loss from operations	(6,309)	(7,144)	(18,217)	(20,748)
Other income (expense), net	268	362	781	1,122
Net income/(loss)	$ (6,041)	$ (6,782)	$ (17,436)	$ (19,626)
Net income/(loss) per common share – basic	$ (0.11)	$ (0.13)	$ (0.32)	$ (0.39)
	-	-	-	-
Wtd Avg common shares outstanding basic and diluted	55,247	50,837	54,161	50,757

Vivani Medical, Inc.
Q3 2024: Balance Sheet*

Condensed Consolidated Balance Sheets (unaudited)

In Thousands	Sept. 30, 2024	Dec. 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,646	$ 20,654
Prepaid expenses and other current assets	1,753	2,408
Total current assets	21,399	23,062
Property and equipment, net	1,644	1,729
Right-of-use assets	18,383	19,616
Restricted cash	1,338	1,338
Deposits and other assets	132	52
Total assets	**$ 42,896**	**$ 45,797**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 6,270	$ 5,723
Long term operating lease liabilities	18,294	19,313
Total liabilities	**24,564**	**25,036**
Stockholders' equity:	-	-
Total Common Stock, APIC & Other Comp Gain	134,206	119,199
Accumulated deficit	(115,874)	(98,438)
Total stockholders' equity	18,332	20,761
Total liabilities and stockholders' equity	**$ 42,896**	**$ 45,797**

* Does not include an additional $5 million in equity financing from a private sale on November 8, 2024

Vivani Medical, Inc.
Q3 2024: Cap Table

As of September 30, 2024

Equity*	WAEP**	Number of Shares
Common Stock		55,266,435
Stock Options	$2.52	6,809,230
RSUs	-	695,000
Warrants	$3.41	9,912,392
Fully Diluted Shares		72,683, 057

* 3,968,253 shares were issued at a price of $1.26 in a private sale on November 8, 2024

**Weighted Average Exercise Price

Vivani Medical, Inc.

1. An innovative, biopharmaceutical company developing a portfolio of ultra long-acting, miniature, drug implants to treat chronic diseases. NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability.

2. Lead program NPM-115 utilizes a miniature, six-month, GLP-1 (high-dose exenatide) implant under development for chronic weight management in obese or overweight patients.

3. Pipeline includes IND-cleared NPM-119 utilizes a miniature, six-month, GLP-1 (exenatide) implant under development for type 2 diabetes and NPM-139 (semaglutide implant), under development for chronic weight management with the potential benefit of once-yearly dosing.

4. Vivani is well-positioned to advance NPM-115 and its pipeline towards potentially transformational milestones in 2024 and 2025.