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 Earliest Event Reported): February 28, 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)**

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

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	**VANI**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On February 28, 2024, Vivani Medical, Inc. (the "Company") issued a press release announcing positive preclinical data on weight loss effects for NPM-115, the Company's miniature, twice-yearly, exenatide implant under development for the treatment of chronic weight management. A copy of the press release is furnished hereto as Exhibit 99.1.

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 in this report (including Exhibits 99. 1 and 99.2, is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. This report will not be deemed an admission as to the materiality of any information in this Item 7.01 (including Exhibits 99.1 and 99.2).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "Vivani Medical Announces Positive NPM-115 Preclinical Weight Loss Data Comparable to Ozempic®/Wegovy® and Discloses NPM-139 as Semaglutide as Strategy Shifts to Prioritize Obesity Portfolio"issued by the Company on February 28, 2024.
99.2	Corporate Presentation as of February 28, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIVANI MEDICAL, INC.

Date: February 28, 2024

By: /s/ Brigid Makes
Brigid Makes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 99.1

FOR IMMEDIATE RELEASE

Vivani Medical Announces Positive NPM-115 Preclinical Weight Loss Data Comparable to Ozempic®/Wegovy® and Discloses NPM-139 as Semaglutide as Strategy Shifts to Prioritize Obesity Portfolio

NPM-115 (exenatide implant) generated significant weight loss comparable to injectable semaglutide (Ozempic®/Wegovy®) from a single administration with expected twice-yearly dosing

Vivani discloses semaglutide as the active pharmaceutical ingredient in NPM-139, with the added potential benefit of once-yearly dosing

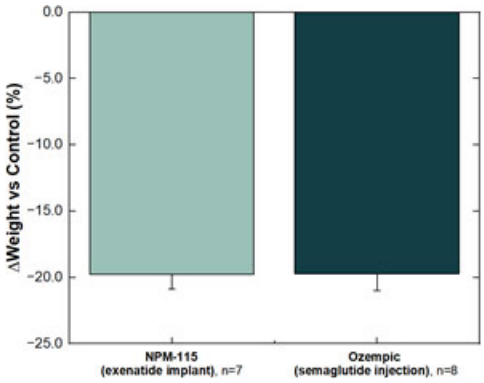
NPM-115 and NPM-139 are miniature, subdermal implants in development for chronic weight management designed to guarantee medication adherence and potentially improve treatment tolerability by providing smooth and steady delivery of GLP-1 therapy

ALAMEDA, Calif., February 28, 2024 -- (BUSINESS WIRE) -- Vivani Medical, Inc. (Nasdaq:VANI) ("Vivani" or the "Company"), an innovative, preclinical-stage biopharmaceutical company developing novel, long-term drug implants, today announced positive preclinical data on weight loss effects for NPM-115, the Company's miniature, twice-yearly, exenatide implant under development for the treatment of chronic weight management. The Company also disclosed that semaglutide is the active pharmaceutical ingredient in NPM-139, a miniature, subdermal GLP-1 implant in development for chronic weight management, with the added potential benefit of once-yearly administration. These developments are part of a strategic shift to prioritize the Company's obesity implants based on emerging data regarding the potential for high-dose GLP-1 products to improve health outcomes for obese and overweight patients.

"In response to tremendous medical need and unprecedented market demand, we are prioritizing the development of our GLP-1 implants for the treatment of obesity and chronic weight management. Since a high-dose GLP-1 implant for obesity would likely also be able to address our previous type 2 diabetes focus, the recently generated compelling weight loss data from NPM-115 naturally supports a shift in focus towards an indication with even broader potential. We believe the primary expected advantages of our proprietary NanoPortal™ implant technology, improving medication adherence and medication tolerability, have the potential to transform and advance the adoption of GLP-1 therapy in the future." said Adam Mendelsohn, Ph.D., Vivani President and Chief Executive Officer. "The potential for long-term GLP-1 implants becomes even more compelling when you consider that the improved adherence and persistence of Ozempic and Wegovy over prior obesity medications is still only 40% as recently reported in a large retrospective cohort study published in the research journal *Obesity*. Collectively, the potential for improvement in medication adherence, tolerability and real-world patient outcomes motivates us to rapidly advance the development of NPM-115, NPM-139 and the balance of our portfolio."

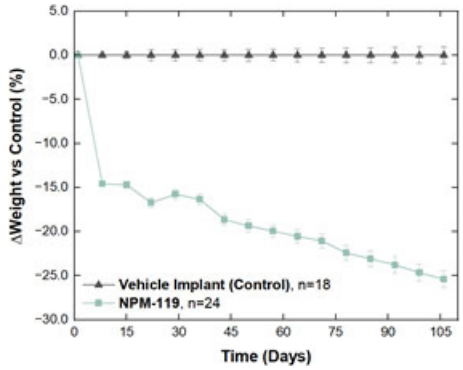
In a study in high-fat diet-induced obese mice, NPM-115 generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to weight loss observed in mice treated with semaglutide injections (Ozempic/Wegovy) in the same study. The supratherapeutic doses provided for both NPM-115 (single administration delivering exenatide at ~530 nmol/kg/day), and semaglutide (weekly injections of ~2,700 nmol/kg/week), were selected to maximize the weight-loss potential of both exenatide and semaglutide.

Weight loss in high fat diet-induced obese mice.% weight change from baseline for NPM-115 (exenatide) vs Ozempic® (semaglutide), corrected to control (sham implant). Values are mean ± SE.



In a second study in healthy rats, a single administration of the Company's exenatide implant NPM-119, in development for the treatment of type 2 diabetes, resulted in body weights that were approximately 25% lower than a vehicle implant control after 15 weeks of treatment with an expected duration of effect of six months. NPM-119 delivered exenatide at a rate of approximately 320 nmol/kg/day and has demonstrated smooth, non-fluctuating release of exenatide in both *in vitro* and *in vivo* studies. NPM-119 has previously demonstrated pharmacokinetic data exhibiting continuous and therapeutic exenatide exposure levels over a six-month duration in healthy rats. Since NPM-115 is a higher-dose version of an otherwise similar product as NPM-119, the durability of the effect on weight demonstrated in this study is expected to translate to future studies utilizing NPM-115.

Weight difference from control in healthy Sprague-Dawley Rats. % weight change from baseline for NPM-119 (exenatide) corrected to control (vehicle implant). Values are mean ± SE.



These preclinical data provide further evidence that the weight loss potential of exenatide treatment in humans may be comparable to other GLP-1 molecules such as semaglutide assuming adequate exposure levels are achieved and maintained. The weight loss potential of exenatide in humans has not been fully evaluated in the currently marketed exenatide products Byetta® (twice-daily injection) and Bydureon® (weekly injection) potentially due to limitations associated with adherence and dosing. NPM-115 directly addresses these limitations. It is designed to improve adherence by enabling patients to receive continuous dosing over a six-month interval from a single administration. NPM-115 is planned to maximize exenatide's weight loss effect in humans, pending further development and regulatory clearance, by evaluating exenatide exposure levels higher than previously explored.

Dr. Mendelsohn will present study results on May 17 at the TIDES USA 2024 conference in Boston.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani Medical develops biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence, and potentially to improve medication tolerability. Vivani's NPM-115 and NPM-119 are miniature, six-month, GLP-1 implants in development for the treatment of chronic weight management in obese or overweight patients and type 2 diabetes, respectively. Both NPM-115 and NPM-119 are exenatide based products with a higher-dose associated with NPM-115 for the treatment of chronic weight management in obese or overweight patients. An IND for NPM-119's first-in-human study LIBERATE-1 has been submitted and is on clinical hold pending requests by the FDA for additional chemistry, manufacturing, and controls (CMC) information. Vivani anticipates submitting the requested CMC information to the FDA in the first half of 2024. LIBERATE-1 is a randomized, 12-week investigation of the safety, tolerability, and full pharmacokinetic profile of NPM-119 in patients with type 2 diabetes. Vivani is also preparing to submit an IND for a first-in-human study with NPM-115 for the treatment of chronic weight management later this year. 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 why obese or overweight patients, and patients taking type 2 diabetes or other chronic disease medications face significant challenges in achieving positive real-world effectiveness.

Vivani's wholly owned subsidiary Cortigent is developing targeted 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. 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 our business, products in development, including the therapeutic potential thereof, plans to address any requests from the FDA related to the agency's current clinical hold on NPM-119, the initiation of the LIBERATE-1 trial and reporting of trial results, the planned development therefor, our emerging development plans for NPM-115, NPM-139, or our 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 our 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 our 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 our products, including NPM-115 and NPM-119; delays and changes in the development of our products, including our ability to address any requests from the FDA related to LIBERATE-1 and to commence clinical development of NPM-119, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct our development activities, risks related to the initiation, enrollment and conduct of our planned clinical trials and the results therefrom; our history of losses and our ability to access additional capital or otherwise fund our 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 SEC filed on March 31, 2023, as updated by our subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by us 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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Exhibit 99.2


Vivani
Nasdaq: VANI
www.vivani.com
Vivani Medical, Inc.
Guaranteed Adherence. Better Outcomes.
February 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 31, 2023, 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

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 Aziyo Biologics
- Involved in/Directed 2 IPOs, 2 reverse mergers and 1 SPAC

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.

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

Vivani Medical, Inc.

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

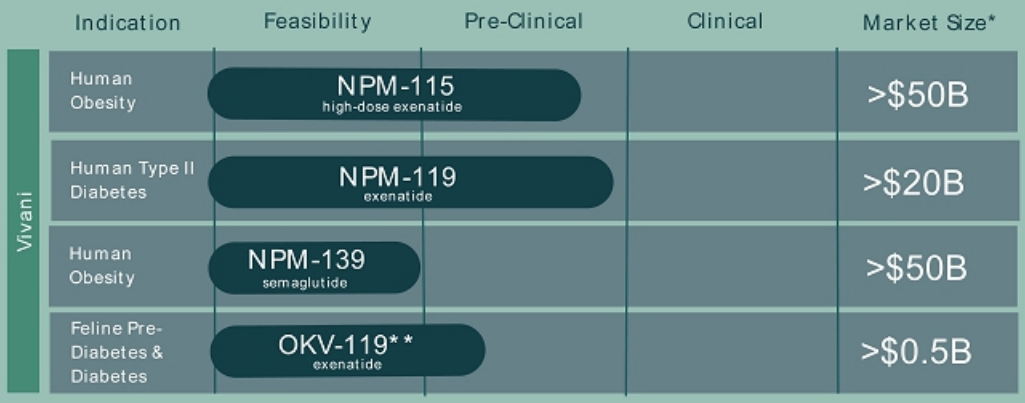
2. Lead programs NPM-115 and NPM-119 are miniature, six-month, GLP-1 (exenatide) implants under development for the treatment of chronic weight management in obese or overweight patients and type 2 diabetes, respectively.

3. NPM-139 (semaglutide implant) is also under development for chronic weight management with the added potential benefit of once-yearly administration.

4. Vivani is well-positioned to advance NPM-115 and NPM-119 towards potentially transformational milestones in 2024.

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 JP Morgan analyst Richard Vosser estimates GLP-1 Market reaches $71 billion by 2032 (9/11/2023). We assume >$20B for type 2 diabetes and >$50B for chronic weight management in obese or overweight patients

** In Partnership with Okava Pharmaceuticals, Inc.


Drug Implants
Proprietary Platform Technology

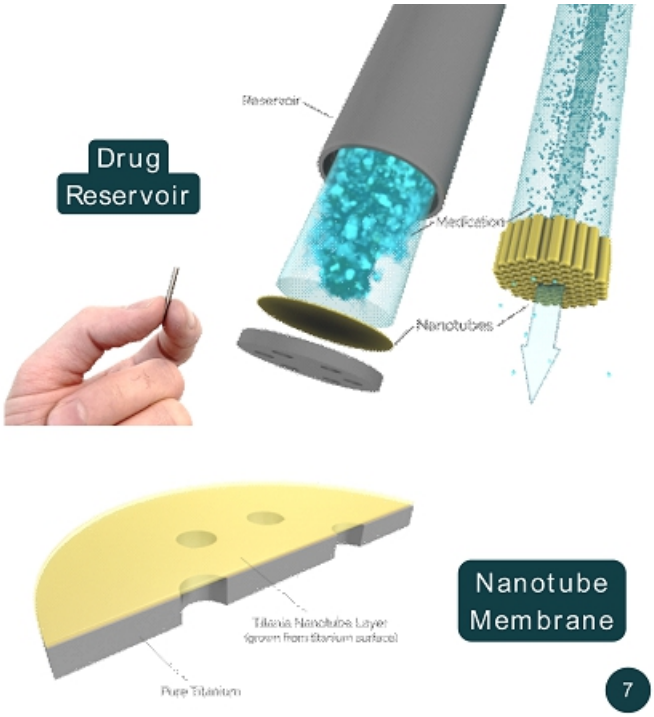
NanoPortal™:

Innovative Delivery Technology

Designed to assure adherence

Minimally-fluctuating and tunable delivery profiles

Potential application with many molecular types

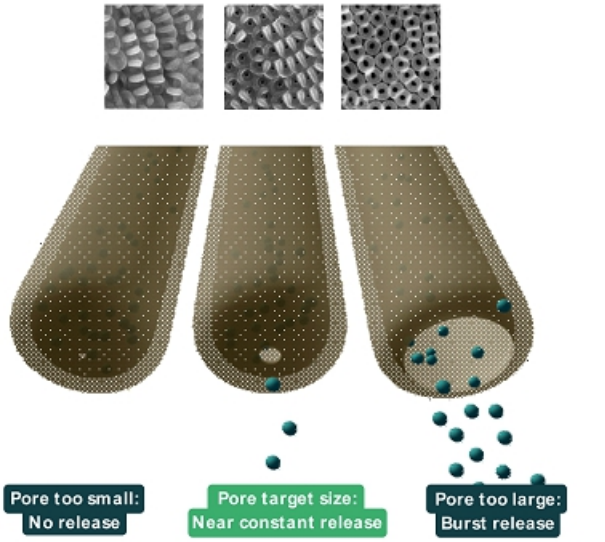


Nanotube Membrane

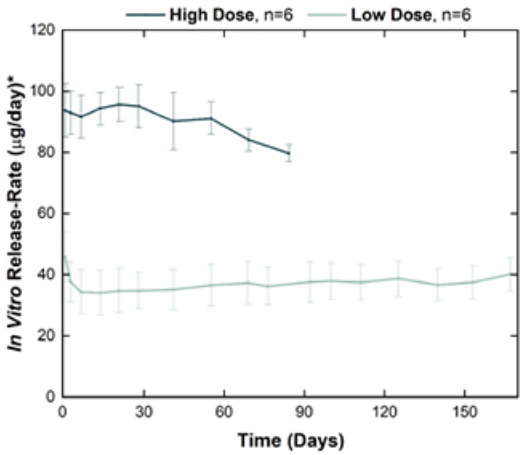
NanoPortal™:

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**

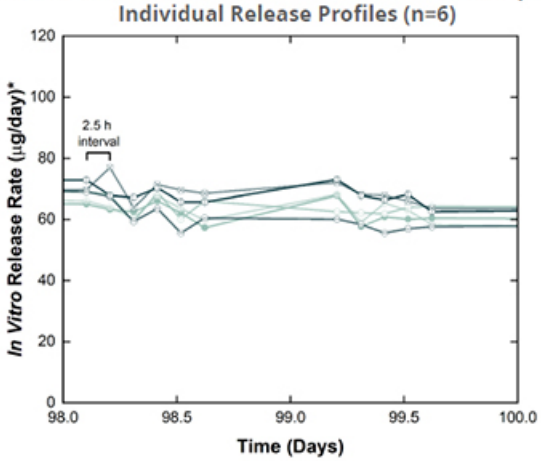


Near-constant and minimally-fluctuating release



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.

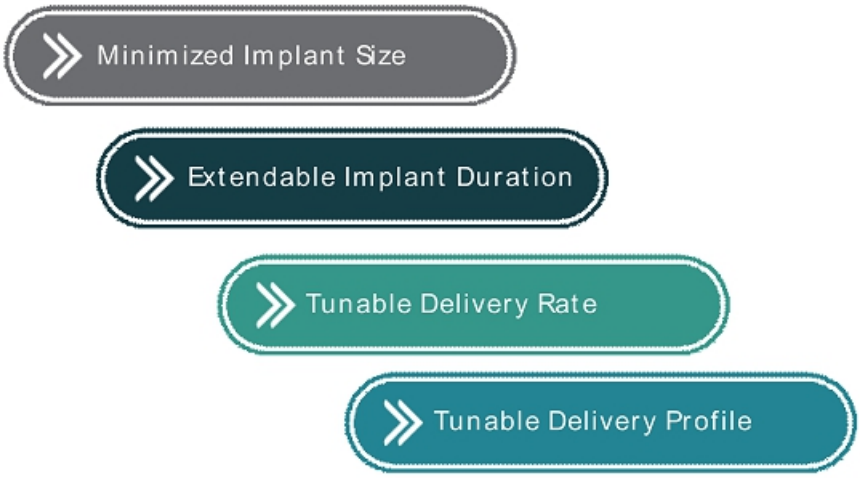
Minimal Fluctuations with 2.5-hour interval sampling
Individual Release Profiles (n=6)



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



Vivani Lead Program
NPM-115

High-Dose Exenatide Implant for Chronic Weight Management

Targeting the Rapidly Growing GLP-1 RA Market

Lead Product NPM-115:

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]
- Preliminary 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

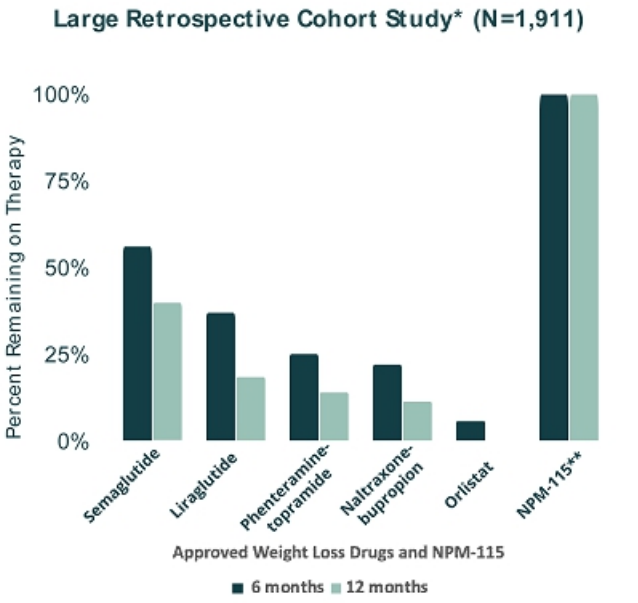
[1,2] Novo Nordisk 2023 Annual Report

Weight Loss Medicines Associated With Adherence Challenges

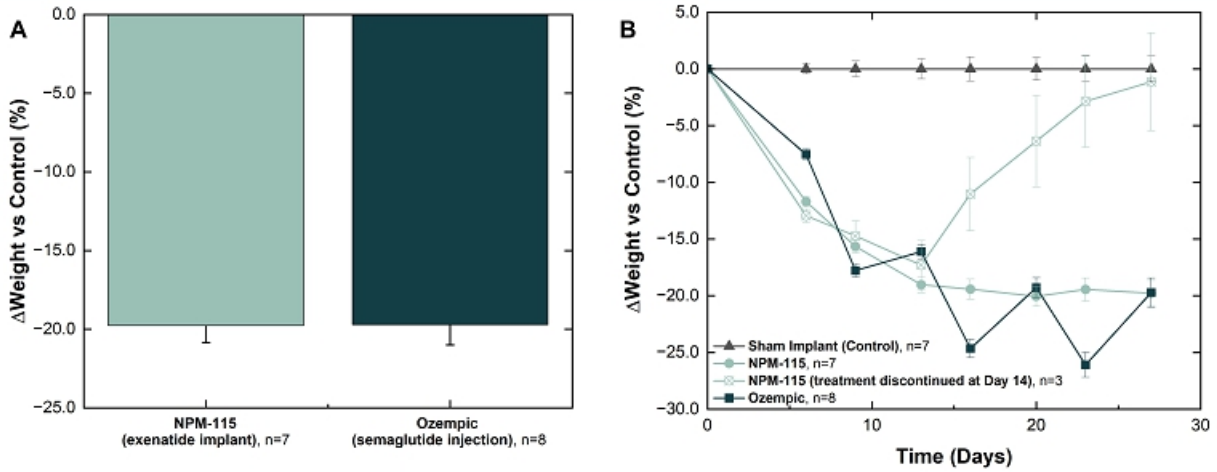
Recent retrospective cohort study (n=1,911) reported improved medication persistence with semaglutide of 40% after one year

- 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 (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.

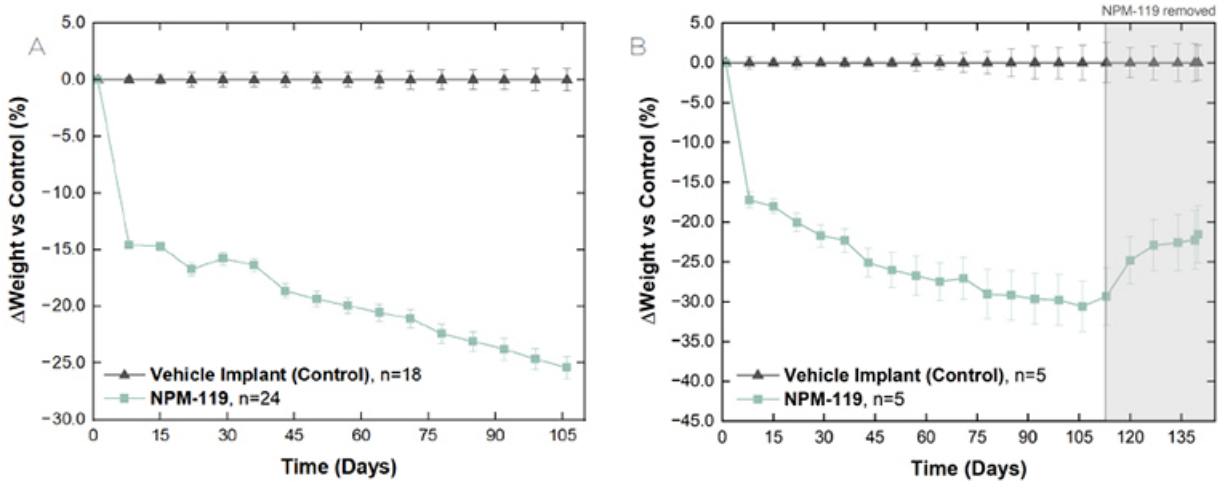


NPM-115 is associated with comparable weight loss to semaglutide in preclinical studies



Weight loss in high fat diet-induced obese mice. (A) % weight change from baseline for a single administration of NPM-115 (exenatide, ~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 NPM-115 (exenatide, ~530 nmol/kg/day) vs. weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant). Values are mean ± SE.

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 NPM-119 (exenatide, ~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.

NPM-115 Clinical + Regulatory Development Near-Term Plan

Year(s)	Milestone	Status
2023	Announced Designation of NPM-115 (high dose exenatide)	November 2023
2024	Reported Positive Weight Loss in Preclinical studies	February 2024
2024	Submit IND filing to FDA for First-In-Human study	Expected 2024

November 2023 – Vivani announced the designation of NPM-115 (high-dose exenatide implant) and initiation of the development program for chronic weight management.

February 2024 – Company reported positive preclinical study results demonstrating comparable weight loss between NPM-115 implant and Ozempic/Wegovy (semaglutide injection).

2024 – Planned submission of an Investigational New Drug Application to support the initiation of a First-in-Human trial of NPM-115 for the treatment of chronic weight management in obese or overweight patients.

Vivani Lead Program
NPM-119

Exenatide Implant for Type 2 Diabetes

Targeting the Rapidly Growing GLP-1 RA Market

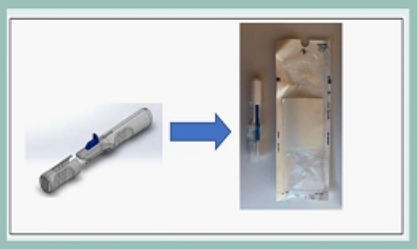
Lead Product (NPM-119):

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

NPM-119 Implant and Applicator



Vivani

Current Drug Adherence Challenge

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

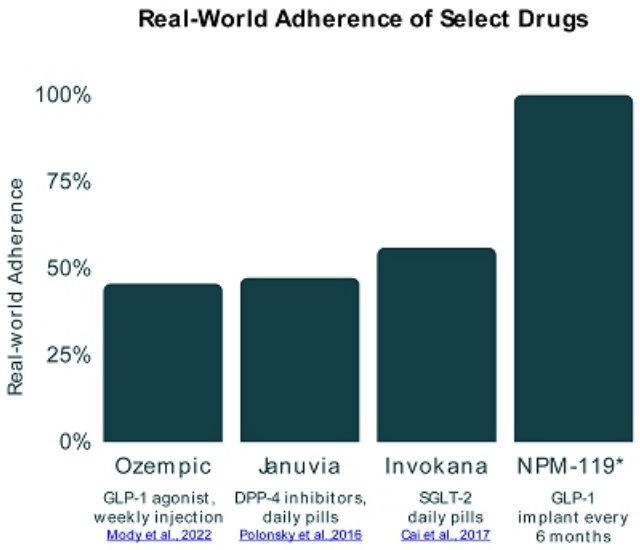
NPM-119* Designed to Enable 100% Adherence through Implant Duration

- 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 – under development, designed to enable 100% adherence, not approved in any market



Intarcia's[1] ITCA 650 (6-month exenatide implant) may be a relevant value analog for NPM-119

Value of long-term GLP-1 (exenatide) implant externally validated previously

2014 – Intarcia signed ITCA 650 deal with Servier (excluding US + Japan) $171M up-front, $880M milestones, and double-digit royalties
– Financings valued Intarcia as high as $4.0B (2017); Intarcia's lead program was ITCA 650

2016 – Intarcia filed initial ITCA 650 New Drug Application (NDA)

2017 – FDA issued the first ITCA 650 CRL[2] (cited manufacturing concerns)

2019 – Intarcia re-submitted ITCA 650 NDA

2020 – FDA issued second ITCA 650 CRL (cited clinical safety and device constituent concerns)

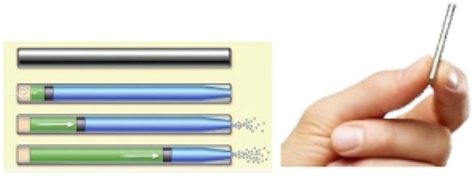
2022 – After dispute resolutions, FDA's CDER proposes to deny Intarcia's public hearing request

2023 – FDA Advisory Board unanimously recommends against the approvability of ITCA 650 due to concerns about safety risks linked to irregular and uncontrolled exenatide release

[1] i2o Therapeutics acquired Intarcia Therapeutic's assets including ITCA-650
[2] CRL: Complete Response Letter – issued by FDA to identify NDA deficiencies

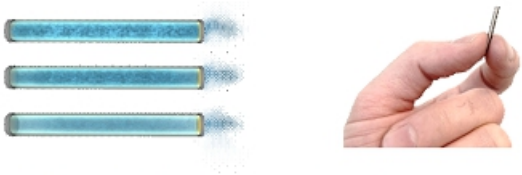
NPM-119 well-positioned to avoid ITCA 650's device technology challenges

Osmotic Pump
(Intarcia)



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

NanoPortal™
(NPM-119)

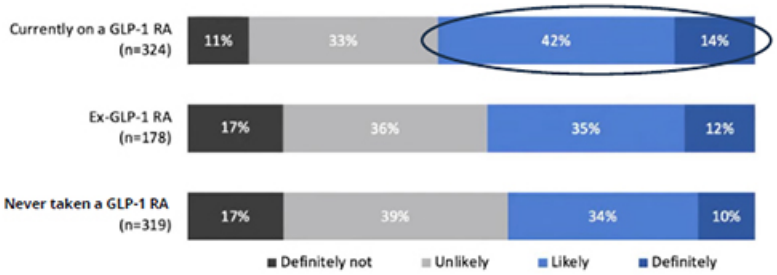


- Minimally fluctuating drug release profile observed in pre-clinical studies
- **Smaller Device** (2.2mm x 21.5mm)
- Insertion using smaller 11-gauge needle

Patient market research indicates strong market 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?"

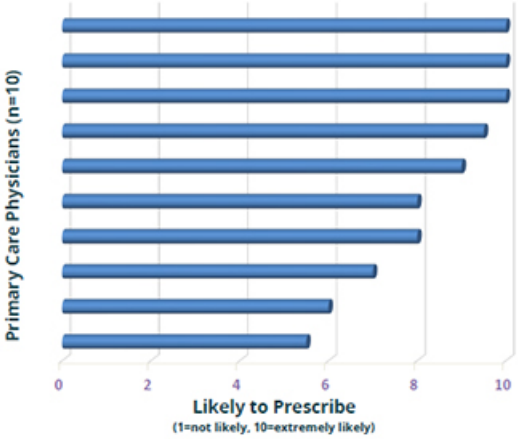
dQ&A

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

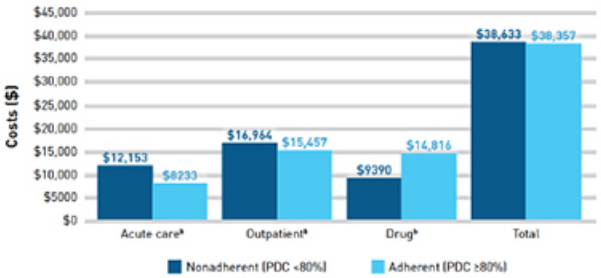
Prescribing Rating, Average 8.3 out of 10

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

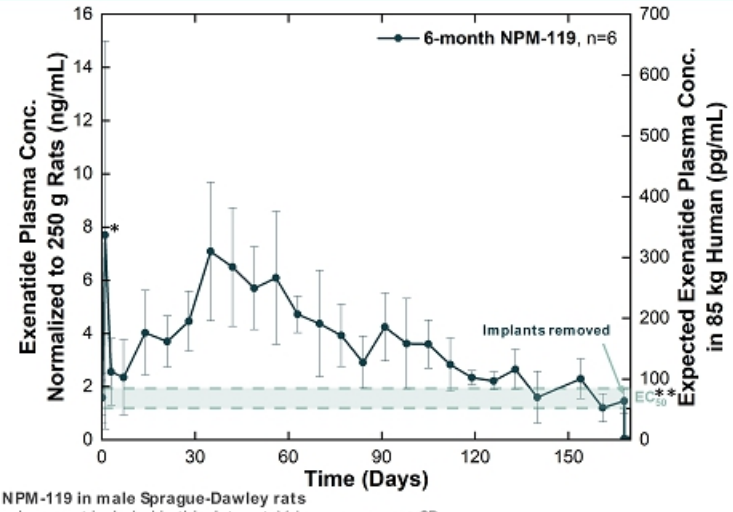
Total: ~$5,500 (annual, per patient)



Curtis et al., 2017

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

6-Month NPM-119 preclinical proof-of-concept achieved



Pharmacokinetics of 6-month NPM-119 in male Sprague-Dawley rats
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

NPM-119
Clinical and Regulatory Pathway

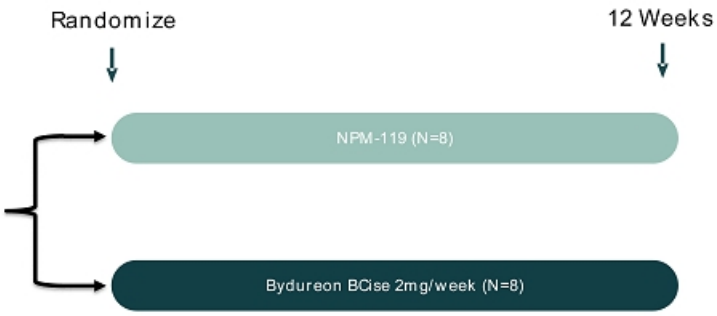
Proposed First-in-Human Trial: LIBERATE-1

Primary Objectives: Safety/tolerability assessment and full PK characterization

Glycemic control (HbA1c) and weight will also be assessed

Key Inclusion/Exclusion Criteria

- T2DM and HbA1c <8.5%
- On non-exenatide GLP-1 therapy (discontinued upon enrollment)
- May be taking their GLP-1 in combination with up to 2 of the following: metformin, TZD, SGLT-2 inhibitor, or DPP-4 inhibitor
- Excluded: SU, insulin



T2DM: Type 2 Diabetes Mellitus; TZD: Thiazolidinedione; SGLT-2: Sodium-glucose cotransporter-2; DPP-4: Dipeptidyl peptidase 4; SU: Sulfonylurea

NPM-119 Clinical + Regulatory Development Near-Term Plan

Year(s)	Milestone	Status
2023	IND filed to support First-in-Human (LIBERATE-1) clinical study	July 14, 2023
2023	FDA provided Clinical Hold letter	August 18, 2023
2024	Generate/Submit New CMC data to Lift Clinical Hold	2024

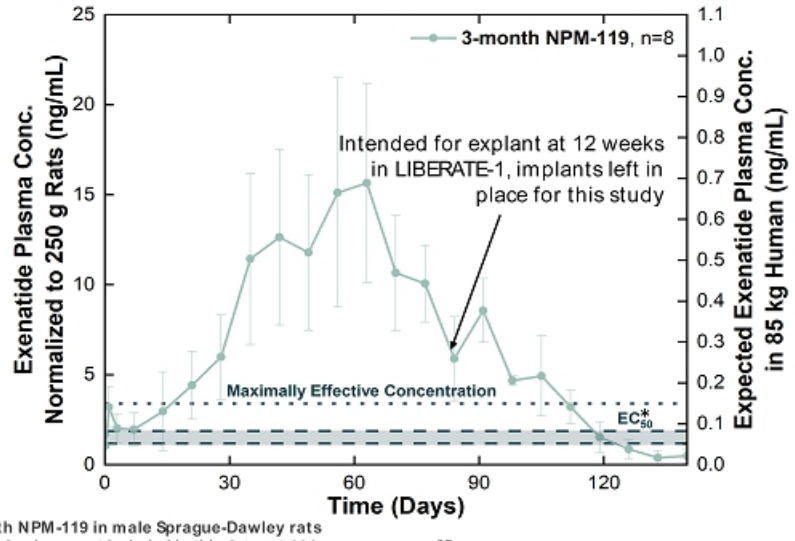
July 14, 2023 – Vivani submitted an Investigational New Drug to support a proposed First in Human study also know as LIBERATE-1 to explore the full pharmacokinetic profile of NPM-119 in patients with type 2 diabetes.

August 18, 2023 – FDA provided a Clinical Hold on the proposed LIBERATE-1 study primarily due to insufficient Chemistry, Manufacturing and Controls (CMC) information.

2024 - Vivani continues to generate the requested CMC information and remains actively engaged in discussions as part of its efforts to lift the Clinical Hold and enable the expeditious initiation of LIBERATE-1. Discussions with FDA to resolve the clinical hold are ongoing.

Vivani currently expects to submit the requested CMC information to the FDA in the first half of 2024.

12-Week NPM-119 PK in Rats



Pharmacokinetics of 3-month NPM-119 in male Sprague-Dawley rats
Exenatide antibody-positive animals are not included in this data set. Values are mean ± SD.
* 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.

Vivani Medical, Inc.
Financial Information

Vivani Medical, Inc.
Q3 2023: P&L Statement

Condensed Consolidated Statements of Operations (unaudited)

In Thousands, except per Share Data	3 Months Ended Sep. 30, 2023	3 Months Ended Sep. 30, 2022	9 Months Ended Sep. 30, 2023	9 Months Ended Sep. 30, 2023
Operating expenses:				
Research and development, net of grants	$ 4,441	$ 3,859	$ 12,260	$ 9,742
General and administrative	2,703	1,585	8,488	3,709
Total operating expenses	7,144	5,444	20,748	13,451
Loss from operations	(7,144)	(5,444)	(20,748)	(13,451)
Other income (expense), net	362	6,867	1,122	6,846
Net income/(loss)	**$ (6,782)**	**$ 1,423**	**$ (19,626)**	**$ (6,605)**
Net income/(loss) per common share – basic	**$ (0.13)**	**$ 0.04**	**$ (0.39)**	**$ (0.18)**
Net income/(loss) per common share – diluted	**$ (0.13)**	**$ 0.04**	**$ (0.39)**	**$ (0.18)**
Weighted average common shares outstanding – basic	**50,837**	**37,965**	**50,757**	**37,712**
Weighted average common shares outstanding – diluted	**50,837**	**38,477**	**50,757**	**37,712**

Vivani Medical, Inc.
Q3 2023: Balance Sheet

Condensed Consolidated Balance Sheets (unaudited)

In Thousands	Sep. 30, 2023	Dec. 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,821	$ 45,076
Prepaid expenses and other current assets	5,861	2,452
Total current assets	30,682	47,528
Property and equipment, net	1,134	1,182
Right-of-use assets	20,050	779
Restricted cash	1,366	1,366
Deposits and other assets	87	275
Total assets	**$ 53,319**	**$ 51,130**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current liabilities	$ 7,433	$ 6,822
Long term operating lease liabilities	19,679	—
Total liabilities	**27,112**	**6,822**
Stockholders' equity:		
Total Common Stock, APIC & Other Comp Loss	118,619	117,094
Accumulated deficit	(92,412)	(72,786)
Total liabilities and stockholders' equity	**$ 53,319**	**$ 51,130**

Vivani Medical, Inc.
Q3 2023: Cap Table

As of September 30, 2023		
Equity	**WAEP***	**Number of Shares**
Common Stock		51,025,060
Stock Options	$2.82	6,043,164
RSUs	$3.15	402,500
Warrants**	$11.13	10,310,543
Fully Diluted Shares		67,781,267

*Weighted Average Exercise Price
**Actual warrants total 15,437,918 including 7,684,313 for Second Sight which when exercised 3 for 1, convert to 2,563,688 common shares

Vivani Medical, Inc.

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

2. Lead programs NPM-115 and NPM-119 are miniature, six-month, GLP-1 (exenatide) implants under development for the treatment of chronic weight management in obese or overweight patients and type 2 diabetes, respectively.

3. NPM-139 (semaglutide implant) is also under development for chronic weight management with the added potential benefit of once-yearly administration.

4. Vivani is well-positioned to advance NPM-115 and NPM-119 towards potentially transformational milestones in 2024.