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 14, 2023

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	VANI	Nasdaq

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 14, 2023, the Company issued a press release entitled "*Vivani Medical Provides Business Update and Reports Third Quarter Financial Results"*, which is attached to this Current Report as Exhibit 99.2.

The information contained in this Item 2.02 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, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 7.01. **Regulation FD Disclosure**

Vivani Medical, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. These slides are attached to this Current Report on Form 8-K as Exhibit 99.1 and are incorporated by reference herein. The Company is also posting to the "Investors" portion of its website a copy of its current corporate slide presentation. The slides speak as of the date of this Current Report on Form 8-K. While the Company may elect to update the slides in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so.

The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the 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, except as shall be expressly set forth by reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	**Description**
99.1	Corporate Slides, dated November 14, 2023.
99.2	Press Release dated November 14, 2023 entitled "*Vivani Medical Provides Business Update and Reports Third Quarter Financial Results"*
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 14, 2023

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


Vivani
Nasdaq: VANI
www.vivani.com
Vivani Medical, Inc.
Guaranteed Adherence. Better Outcomes.
November 14, 2023

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-119 or otherwise commence our planned clinical trial for this product 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:
- COO 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 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 disease. Our NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability.

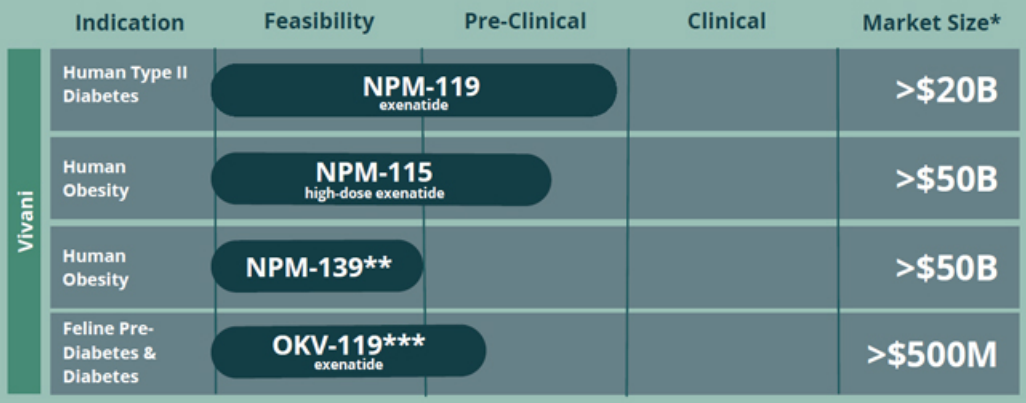
2. Lead programs NPM-119 and NPM-115 are miniature, six-month, GLP-1 implants under development for the treatment of type 2 diabetes and chronic weight management in obese or overweight patients, respectively.

3. Vivani's pipeline also contains NPM-139, using an undisclosed molecule, with the potential for once-yearly administration.

4. Vivani is well-positioned to advance NPM-119 and NPM-115 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 obesity
** Feasibility in progress with a non-exenatide compound in collaboration with an undisclosed major pharma company
*** In Partnership with Okava Pharmaceuticals, Inc.

Drug Implants
Proprietary Platform Technology

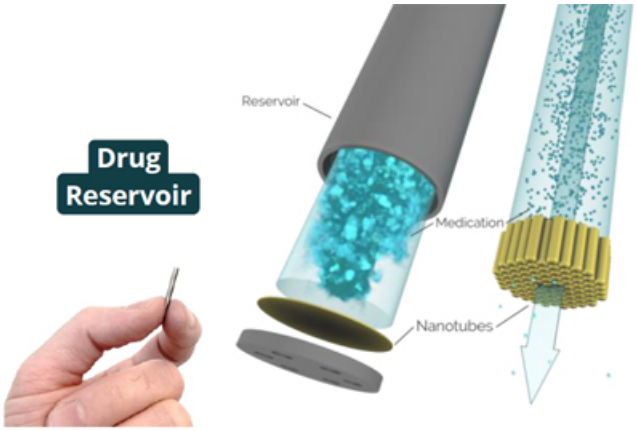
NanoPortal:

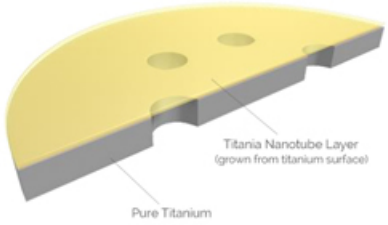
Innovative Delivery Technology

Designed to Assure Adherence

Minimally-fluctuating and tunable delivery profiles

Potential application with many molecular types



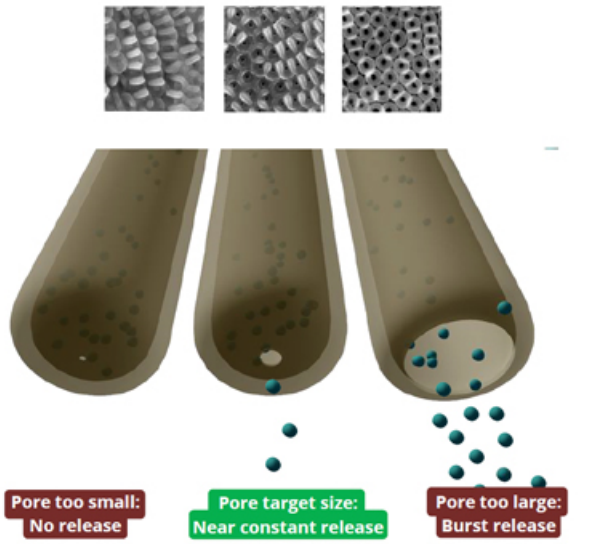


Nanotube Membrane

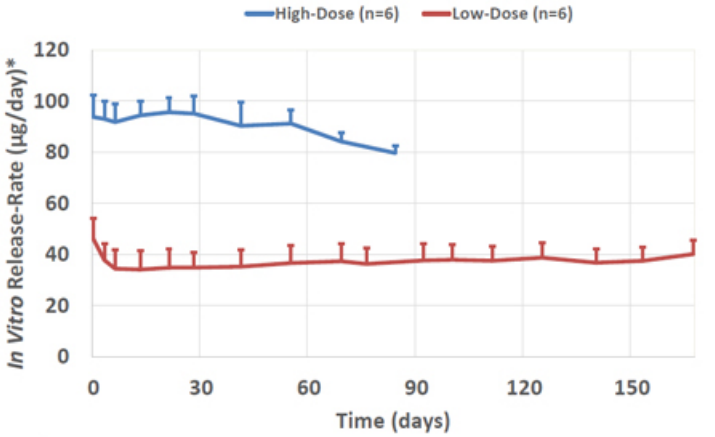
NanoPortal:

How it Works...

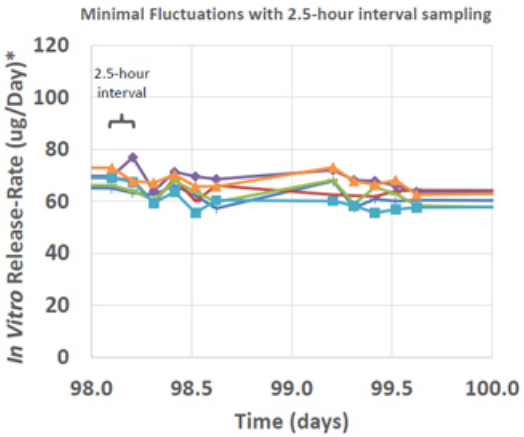
By precisely adjusting nanotubes to molecule size, interactions between drug and nanotube walls can result in desirable release profiles over time, including **near constant release**



Near-constant and minimally-fluctuating release



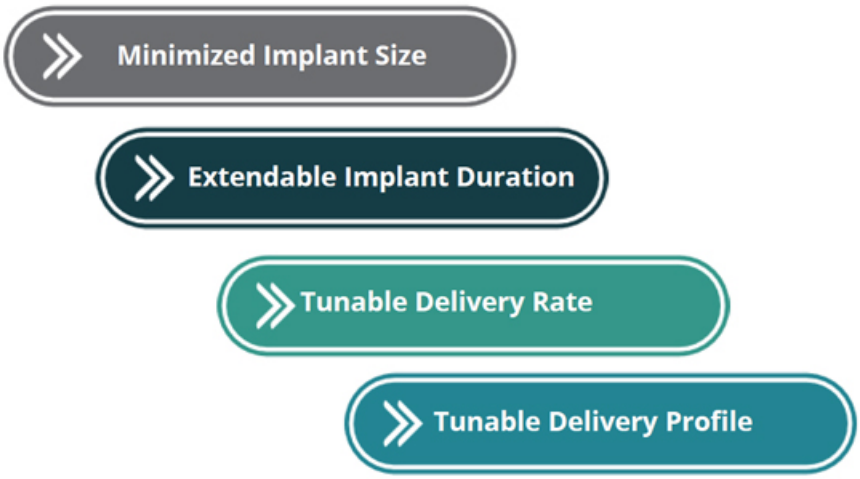
*Release-rates include exenatide and related substances. Day 1 timepoint includes cumulative release over the first day including a separately measured 1st hour of release, which was ~7 µg for the high-dose and ~4 µg for the low-dose.



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's Lead Program
NPM-119

Targeting the Rapidly Growing GLP-1 RA Market

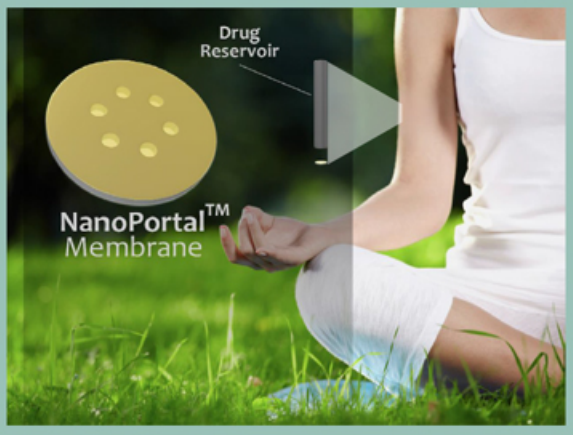
Lead Product (NPM-119):

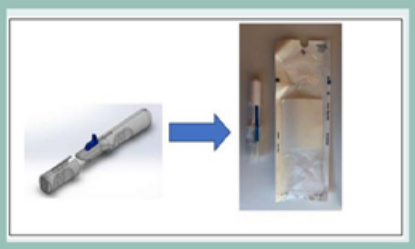
6-Month Exenatide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Type 2 Diabetes

- Non-adherence is the primary reason for low, real-world effectiveness[1,2]
- Guaranteed adherence will produce significant healthcare cost savings[3]
- FDA indicated 505(b)(2) streamlined approval pathway may be available
- ~$54M raised pre-merger from investors including AstraZeneca

1 Guo 2016
2 Carls et al., 2017
3 IMS 2013 Report

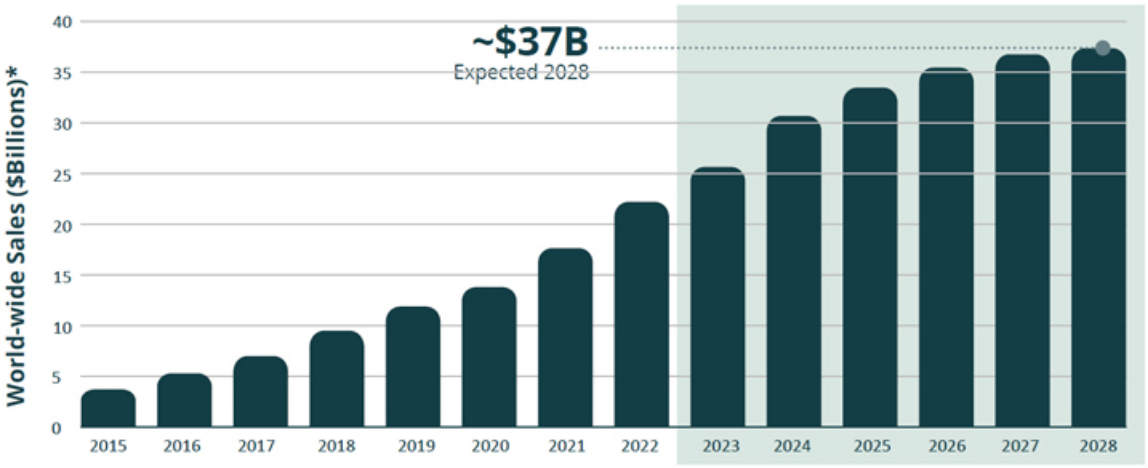
NPM-119 Implant and Applicator





Vivani

The GLP-1 Market is very large and growing rapidly



- Adopted from Evaluate Pharma
- JP Morgan analyst Richard Vosser estimates GLP-1 Market to reach $71 billion by 2032, September 11, 2023

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

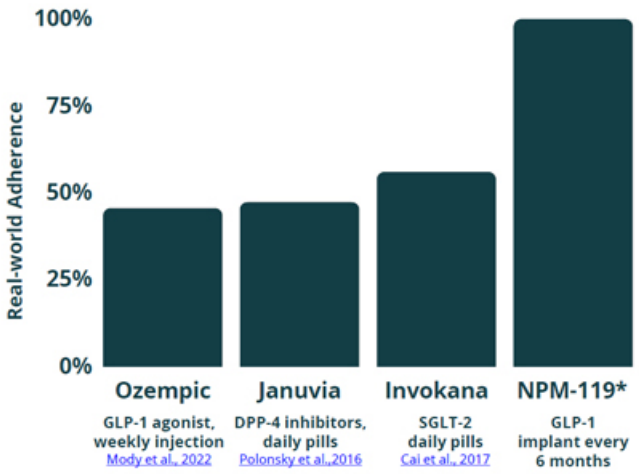
- Orals and injectables do not guarantee adherence
- Approximately 50% of patients do not meet glycemic targets primarily due to nonadherence

Dual Incentive to Adopt Technology that Improves Adherence

- Pharmaceutical revenue is increased
- Healthcare costs are decreased

* NPM-119 – under development, not approved in any market

Real-World Adherence of Select Drugs



* NPM-119 designed to enable 100% adherence.

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)

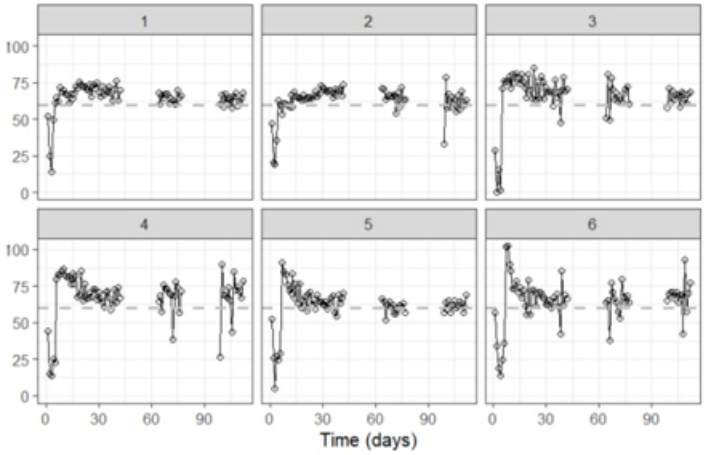
- FDA alleges that **daily variations in drug release** may be responsible for **clinical safety signals**
- **Larger Device** (4mm x 45mm)
- Insertion using **larger 6-gauge needle**

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**

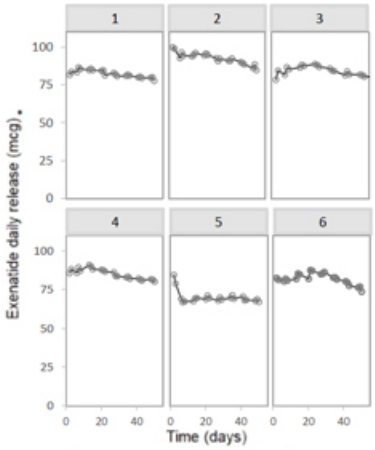
ITCA-650 and NPM-119 Intra Device Daily *In Vitro* Release Fluctuation Comparison

Osmotic Pump (ITCA 650, through Day 100)



Data presented by FDA on September 21, 2023, ITCA 650 Advisory Board Hearing (first 6 of 12 devices)

NanoPortal™ (NPM-119, N=6)

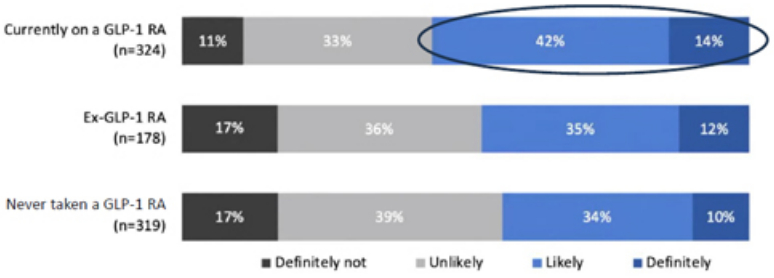


*Includes Exenatide and Related Substances, Interim Data from Vivani Study

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?"

19

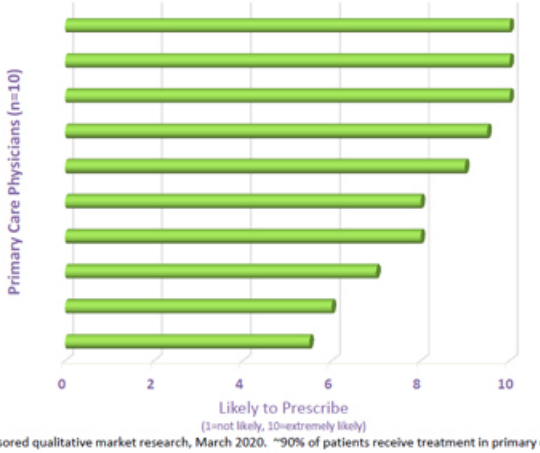
dQ&A

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

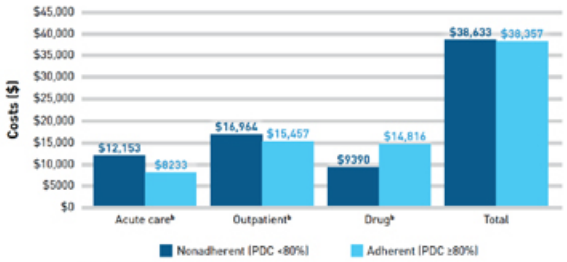
Rating: Overall, using a scale of 1 to 10, where 1 is not at all likely and 10 is extremely likely, how likely are you to prescribe NPM-119?



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

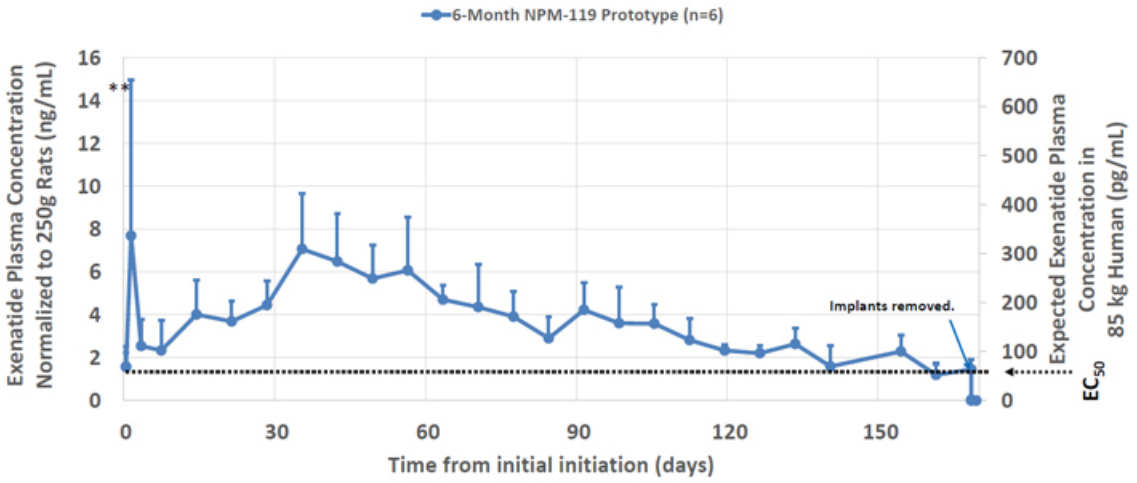
Adherence = Lower Acute Care and Outpatient Costs

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



Curtis et al., 2017

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



* Exenatide antibody-positive animals are not included in this data set.
**2 of 6 implants are responsible for higher Day 1 exenatide concentrations. Additional optimization ongoing to yield consistent gradual initial PK profiles.

NPM-119
Clinical and Regulatory Pathway

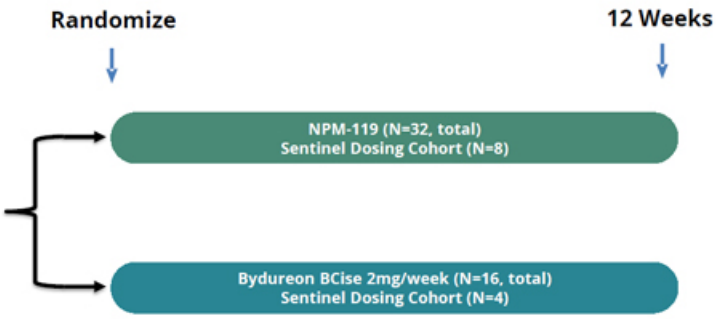
Proposed First-in-Human Trial: LIBERATE-1*

Primary Objectives: Safety/tolerability assessment and full PK characterization

Secondary Objective: Evaluate change from baseline in glycemic control (HbA1c)

Key Inclusion/Exclusion Criteria

- T2DM and HbA1c ≥6.5% and <9.5%
- 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



*** Trial design subject to change pending ongoing FDA discussions regarding the current Clinical Hold**

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

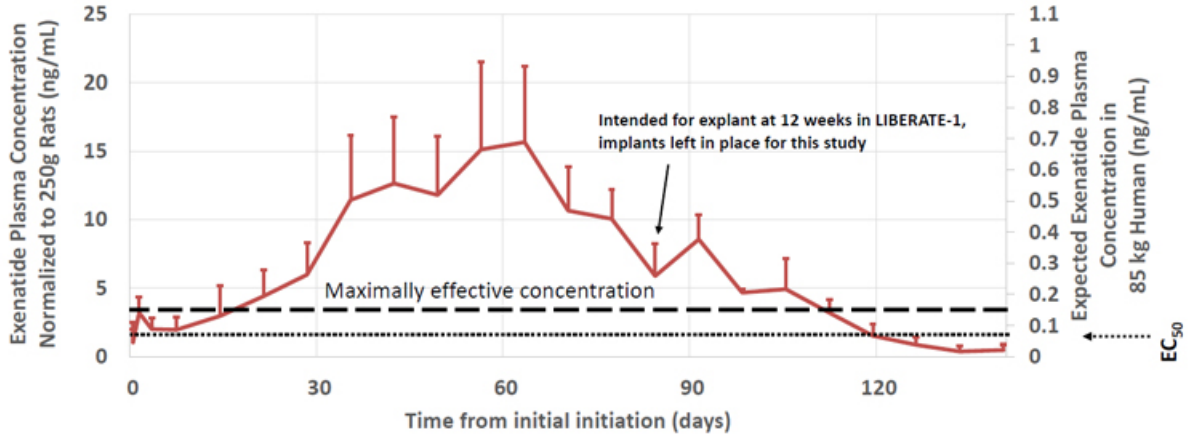
Year(s)	Milestone	Status
2023	IND filed to support First-in-Human (LIBERATE-1) clinical study	July 14, 2023
2023	FDA provided Clinical Hold letter	August 18, 2023
2023	Type A face-to-face meeting with FDA	October 19, 2023

August 18, 2023 – FDA provided written notification of a Clinical Hold on the proposed LIBERATE-1 study exclusively due to insufficient Chemistry, Manufacturing and Controls (CMC) information to assess risks to human subjects. The requested information was related to the assessment of device risks and device performance.

October 19, 2023 – Vivani met with FDA 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 clinical hold are ongoing.

In parallel, Vivani plans to submit an application to a Human Research Ethics Committee in Australia to support the initiation of a first-in-human trial while continuing our efforts to lift the clinical hold with the FDA.

12-Week NPM-119 PK in Rats (n=8)



* Exenatide antibody-positive animals are not included in this data set.

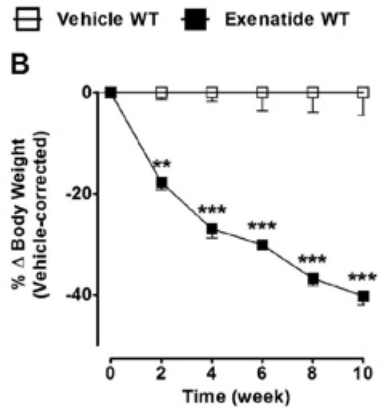
NPM-115:

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 pre-clinical data demonstrated similar magnitude of weight loss for exenatide and semaglutide[3]
- 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

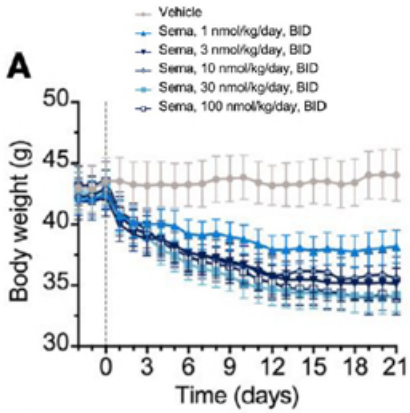
[1, 2] Novo Nordisk 2023 Annual Report
[3] Data not generated from Head-to-Head studies; Individual studies included: Tatarkiewicz et al. 2014 (exenatide) and Gabery et al., 2020 (semaglutide)

Exenatide is associated with comparable weight loss to semaglutide in preclinical studies



Exenatide caused **~23% weight loss after 3 weeks** in **diet-induced obese** mice when delivered at 30 nmol/kg/day[1]

1. Tatarkiewicz et al. 2014



Semaglutide caused **~23% weight loss after 3 weeks** in **diet-induced obese** mice when delivered at 30 nmol/kg/day[2]

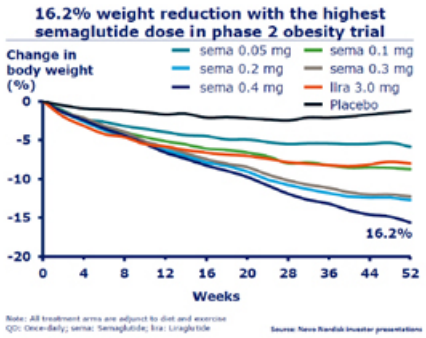
2. Gabery et al., 2020

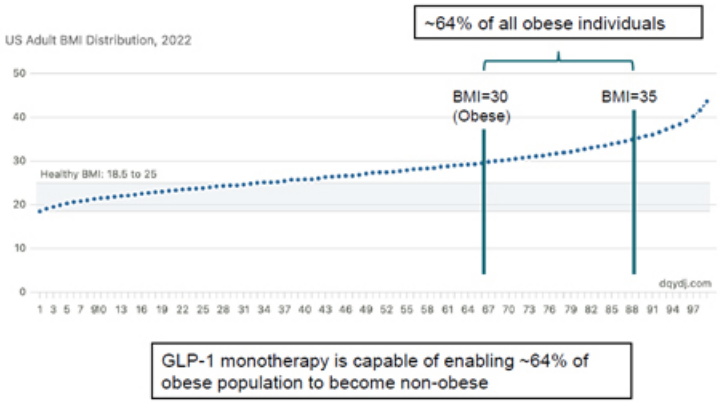
NPM-119 caused **~16.6% lower weight correlated with food consumption** in **healthy** Sprague-Dawley rats compared with vehicle implant control **after 3 weeks.** Weight difference was maintained through the full 16 weeks of treatment.

Semaglutide caused **~16% lower weight** in **healthy** Sprague-Dawley rats **after ~3 weeks.**[3]

3. Cawthon et al., 2023

GLP-1 monotherapy provides adequate weight loss for most obese patients





GLP-1 monotherapy is capable of enabling ~64% of obese population to become non-obese

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.

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Don Dwyer, MBA, Chief Business Officer: don@vivani.com
Website: www.vivani.com

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

3. **Vivani's pipeline also contains NPM-139, using an undisclosed molecule, with the potential for once-yearly administration.**

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

Exhibit 99.2

FOR IMMEDIATE RELEASE

Vivani Medical Provides Business Update and Reports Third Quarter Financial Results

Company announces addition of NPM-115 (high-dose exenatide implant) to its emerging pipeline, a potential alternative to life-long injections or pills for long-term GLP-1 therapy for the treatment of chronic weight management in obese or overweight patients

Vivani is actively engaged in discussions with the US FDA to enable the expeditious initiation of LIBERATE-1, proposed FIH study of NPM-119 in patients with type 2 diabetes; in parallel the Company also plans to submit application to support initiation of the FIH study in Australia

ALAMEDA, Calif., November 14, 2023 -- (BUSINESS WIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), an innovative, preclinical-stage biopharmaceutical company developing novel, long-term drug implants, today reported financial results for the third quarter of 2023 and provided a business update.

Vivani™ continues to advance its emerging pipeline of innovative, highly differentiated drug implants leveraging its proprietary NanoPortal™ subdermal implant technology designed to guarantee medication adherence and improve patient outcomes in the treatment of chronic diseases.

"At Vivani, we continue to make progress in the development of our pipeline of miniature, long-term drug implants designed to improve the treatment of chronic diseases including obesity and type 2 diabetes." said Adam Mendelsohn, Ph.D., Vivani President and Chief Executive Officer. "We are excited to announce the addition of NPM-115 (high-dose exenatide implant) under development for the treatment of chronic weight management in obese or overweight patients to our emerging portfolio. Although the initial focus of our exenatide implant has been for the treatment of type 2 diabetes, the implant was associated with ~16.6% lower weight than a vehicle control implant and the weight loss was substantially maintained throughout the full 16-week treatment period in non-obese Sprague-Dawley rats. This result is consistent with the magnitude of weight loss reported in the literature from a separate study that administered semaglutide, the drug substance in blockbuster products Ozempic®, Wegovy®, and Rybelsus®, in the same animal model. We believe that NanoPortal has the potential to both address the medication adherence challenges associated with the currently marketed exenatide products and provide higher, more efficacious dosing, thereby enabling patients to receive exenatide's maximum potential benefits in both clinical and real-world settings. Given the extraordinary adoption of GLP-1 products for the treatment of obesity, Vivani intends to emphasize NPM-115 and advance the program towards human testing."

Dr. Mendelsohn continued: "Regarding NPM-119 (6-month exenatide implant) under development for the treatment of type 2 diabetes, Vivani remains actively engaged in discussions with the FDA as part of our efforts to lift the clinical hold, which is exclusively related to outstanding CMC information requests, and enable the expeditious initiation of LIBERATE-1, our First-In-Human ("FIH") study in patients with type 2 diabetes. In addition, we are announcing parallel plans to pursue the initiation of the FIH study in Australia. Lastly, we continue to make steady progress with NPM-139, another promising treatment for obesity with the added potential for a once-yearly treatment duration."

Third Quarter Business Highlights

Vivani is announcing the addition of NPM-115 (high-dose exenatide implant) under development for chronic weight management in obese or overweight patients to its emerging pipeline. Preliminary evidence suggests NPM-115, if successful, may provide another competitive GLP-1 monotherapy treatment option with potential advantages associated with improved medication adherence and tolerability. In addition, NPM-115 may provide an attractive alternative to life-long injections or pills for long-term maintenance of GLP-1 therapy for chronic weight management.

On July 14, 2023, the Company submitted an Investigational New Drug application to the U.S. Food and Drug Administration (FDA) for the proposed NPM-119 FIH study LIBERATE-1 in patients with type 2 diabetes.

On August 18, 2023, the FDA provided written notification that the LIBERATE-1 study was on full clinical hold exclusively because of insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. Vivani remains actively engaged in discussions with the FDA as part of its efforts to lift the clinical hold and enable the expeditious initiation of LIBERATE-1.

In parallel, Vivani plans to submit an application to a Human Research Ethics Committee in Australia to support the initiation of the Company's FIH study in that country. If available, Vivani intends to utilize research and development incentives and rebates from the Australian government in order to defray a portion of the costs from the trial. Since clinical studies conducted in Australia comply with the International Conference on Harmonization guidelines and data generated in Australia are acceptable to the FDA and other regulatory authorities, Vivani plans to use relevant clinical data generated in Australia to support regulatory submissions in other geographies including the US. Additional guidance will be provided as new information becomes available.

LIBERATE-1 is a randomized, 12-week investigation of the safety, tolerability, and full pharmacokinetic profile of NPM-119 (GLP-1) implant in patients with type 2 diabetes. LIBERATE-1 will enroll patients who have been on a GLP-1 therapy, which will be discontinued prior to receiving either NPM-119 or the active comparator Bydureon BCise® (exenatide extended-release injectable suspension 2mg).

On July 6, 2023, Vivani changed its state of incorporation from the State of California to the State of Delaware by means of a plan of conversion, effective July 5, 2023. The reincorporation, including the principal terms of the plan of conversion, was submitted to a vote of, and approved by Vivani's stockholders at its 2023 Annual Meeting of Stockholders held on June 15, 2023.

Moving forward, Vivani will focus on the further development of NPM-119, NPM-115 and its emerging pipeline of innovative, miniature, long-term drug implants to treat patients with chronic diseases. Vivani has grown to 36 full-time employees, which does not include the 14 Cortigent employees of whom some have been furloughed, and Vivani's new headquarters are in Alameda, California.

Third Quarter ended September 30, 2023, Financial Results

Cash Balance: As of September 30, 2023, Vivani had cash, cash equivalents and restricted cash totaling $26.2 million compared to $46.4 million as of December 31, 2022. The decrease of $20.2 million is attributed to the $19.6 million operating loss plus a net increase in net operating assets of $3.0 million, offset partially by $2.4 million of non-cash charges. The Company believes its cash and cash equivalents as of September 30, 2023, are estimated to be sufficient to fund operations into early 2025.

Research and development expense. Research and development expense increased by $0.5 million, or 15%, to $4.4 million in the third quarter of 2023 from $3.9 million in the third quarter of 2022. The costs increased due to costs of our acquired company Second Sight being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the quarter by $0.3 million. The remainder of the increase was primarily due to drug implant development costs.

General and administrative expense. General and administrative expense increased $1.1 million, or 71%, to $2.7 million in the third quarter of 2023 from $1.6 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of our acquired company Second Sight which increased $0.6 million in the third quarter of 2023 versus the partial quarter of 2022 which only included one month from the merger date, higher costs associated with being a public company for D&O insurance and professional fees, and higher payroll related expenses.

Other income (expense). Other income was impacted by the merger acquisition of cash which increased our interest income to $0.4 million for the three months ended September 30, 2023. The quarter ended September 30, 2022 was impacted by the gain on bargain purchase of $6.9 million recorded on the purchase of Second Sight at the time of the merger.

Net Loss: The net loss was $6.8 million as compared to net income of $1.4 million for the three-months ended September 30, 2023, and 2022, respectively. The $8.2 million change in net loss/income was primarily attributable to the bargain purchase gain of $6.9 million recorded on the purchase of Second Sight and by a $1.0 million increase from the inclusion of Cortigent expenses which were not included in 2022 prior to the merger, and increased salaries and costs of being a public company.

Year to Date September 30, 2023, Financial Results

Research and development expense. Research and development expense increased by $2.6 million, or 26%, to $12.3 million in the first nine months of 2023 from $9.7 million in the same period of 2022. The costs increased due to costs of our acquired company Second Sight being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the period by $1.4 million. The remainder of the increase was primarily due to drug implants development costs and increased payroll related costs.

General and administrative expense. General and administrative expense increased $4.8 million, or 129%, to $8.5 million in the first nine months of 2023 from $3.7 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of our acquired company Second Sight which increased $2.7 million in the first nine months of 2023 versus the partial inclusion of one month in 2022 after the merger date, higher public company costs and higher payroll related expenses.

Other income (expense). Other income was impacted by the merger acquisition of cash which increased our interest income to $1.1 million for the nine months ended September 30, 2023. The income for the nine months ended September 30, 2022 included $6.9 million for the gain on bargain purchase from the acquisition of Second Sight.

Net Loss: The net loss was $19.6 million as compared to $6.6 million for the nine-months ended September 30, 2023, and 2022, respectively. The $13.0 million increase in net loss was primarily attributable to the bargain purchase gain of $6.9 million recorded on the purchase of Second Sight and a $4.3 million increase from the inclusion of Cortigent expenses, which were not included in 2022 prior to the merger, and increased salaries and costs of being a public company.

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 tolerance to their medication. Vivani's lead programs, NPM-119 and NPM-115, are miniature, six-month, GLP-1 implants in development for the treatment of type 2 diabetes and chronic weight management in obese or overweight patients, respectively. Both NPM-119 and NPM-115 are exenatide based products with a higher-dose associated with NPM-115 for the treatment of 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 why obese or overweight patients, and patients taking type 2 diabetes or other chronic disease treatments 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. The company 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 our business, products in development, including the therapeutic potential thereof, the planned development therefor, 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, 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-119 and NPM-115; delays and changes in the development of our products, 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, including our ability to address any requests from the FDA related to LIBERATE-1 and to commence clinical development of NPM-119; 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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VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	September 30, 2023	December 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:		
Accounts payable	$ 1,891	$ 1,177
Accrued expenses	1,815	2,358
Litigation accrual	1,675	1,675
Accrued compensation expense	676	657
Current operating lease liabilities	1,376	955
Total current liabilities	7,433	6,822
Long term operating lease liabilities	19,679	—
Total liabilities	27,112	6,822
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: 51,025 as of September 30, 2023 and 50,736 as of December 31, 2022, respectively	5	5
Additional paid-in capital	118,568	117,054
Accumulated other comprehensive loss	46	35
Accumulated deficit	(92,412)	(72,786)
Total stockholders' equity	26,207	44,308
Total liabilities and stockholders' equity	$ 53,319	$ 51,130

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except per share data)

	For the Three Months ended September 30,		For the Nine Months ended September 30,	
	2023	**2022**	**2023**	**2022**
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