

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): May 15, 2023

VIVANI MEDICAL, INC.

(Exact name of registrant as specified in its charter)

**California**  
(State or other jurisdiction of  
incorporation)

**001-36747**  
(Commission  
File Number)

**02-0692322**  
(IRS Employer  
Identification No.)

**5858 Horton Street, Suite 280**  
**Emeryville, California**  
(Address of principal executive offices)

**94608**  
(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 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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 15, 2023, the Company issued a press release entitled “*Vivani Medical Reports First Quarter Financial Results and Provides Business Update*”, 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.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Corporate Slides, dated May 15, 2023.</a>
<a href="#">99.2</a>	<a href="#">Press Release dated May 15, 2023 entitled “<i>Vivani Medical Reports First Quarter Financial Results and Provides Business Update</i>”</a>
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: May 15, 2023

By: /Donald Dwyer/Donald Dwyer  
Chief Business Officer



Nasdaq: VANI  
[www.vivani.com](http://www.vivani.com)

# Vivani Medical, Inc.

*Guaranteed Adherence. Better Outcomes.*

May 15, 2023

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# 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 Phase 2 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 Nano Precision Medical 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 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 Nano Precision Medical 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 proprietary, NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability, barriers to patients receiving the full potential benefits of their medicine.
- 2 Lead program NPM-119 is a miniature, 6-month, GLP-1 implant under development for the treatment of patients with type 2 diabetes (T2D) and obesity. Our Phase 2 clinical study of NPM-119 in T2D patients, named LIBERATE-1, is on schedule to start in 2023.
- 3 In March, we announced the proposed initial public offering of our Neuromodulation Division, renamed Cortigent, Inc. This allows Vivani to focus on our drug implant business.
- 4 Vivani is well-positioned with new leadership and sufficient capital to support multiple milestones for NPM-119 and our emerging pipeline of innovative therapeutic implants.

# Company Pipeline


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

	Indication	Feasibility	Pre-Clinical	Clinical	Market Size*
Vivani	Human Type II Diabetes and Obesity	NPM-119 exenatide			>\$20B
	Feline Pre-Diabetes & Diabetes	OKV-119** exenatide			>\$500M
	NASH (Non-Alcoholic Steatohepatitis)	NPM-159*** proprietary compound			>\$18B
	Human Obesity	NPM-139*** proprietary compound			>\$19B

\* Estimated Market Sizes where Vivani candidates would compete, if approved; Does not represent future sales or revenue estimates of Vivani candidates

\*\* In Partnership with Okava Pharmaceuticals, Inc.

\*\*\* Feasibility in progress with a non-exenatide compound in collaboration with an undisclosed major pharma company



**Drug Implants**  
**Proprietary Platform Technology**

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# NanoPortal: Innovative Delivery Technology



Designed to Assure Adherence



Minimally-fluctuating and tunable delivery profiles



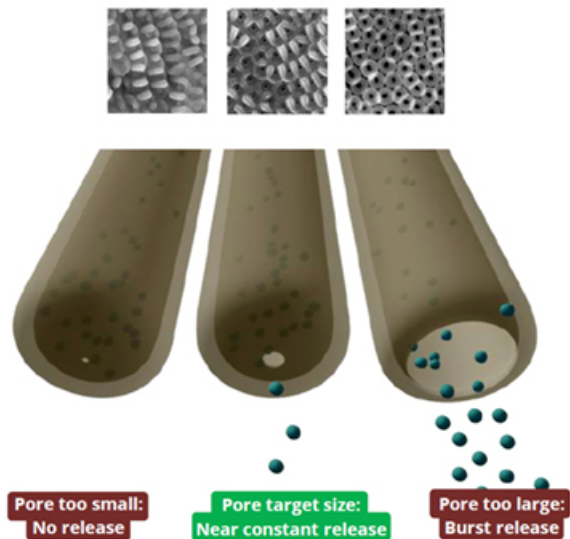
Potential application with many molecular types



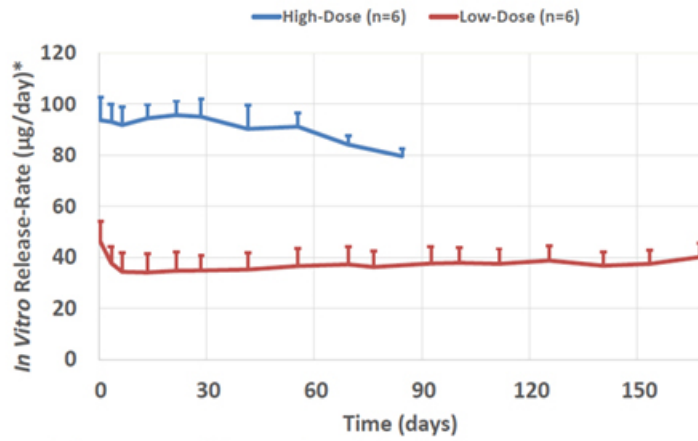
# NanoPortal:

## How it Works...

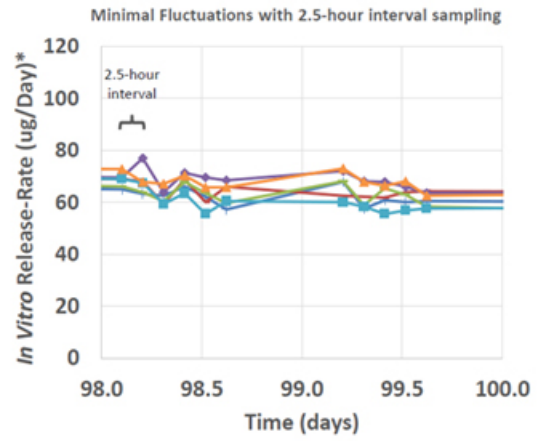
By precisely adjusting nanotubes to molecule size, interactions between drug and nanotube walls can result in desirable release profiles over time, including **near constant release**



# 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 1<sup>st</sup> 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

» Minimized Implant Size

» Extendable Implant Duration

» Tunable Delivery Rate

» Tunable Delivery Profile

# Vivani's Lead Program NPM-119

Targeting the Rapidly Growing GLP-1 RA Market  
>\$20B in 2022 & >\$35B Expected in 2028

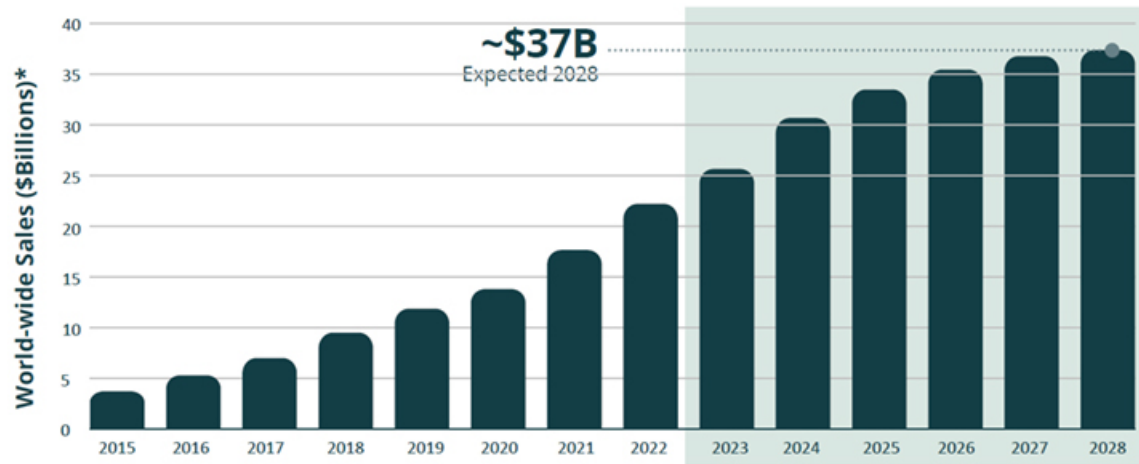
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## **Lead Product (NPM-119): 6-Month Exenatide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Type 2 Diabetes and Obesity**

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

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

## The GLP-1 Market is Very Large and Growing Rapidly



\* Adopted from Evaluate Pharma

# 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

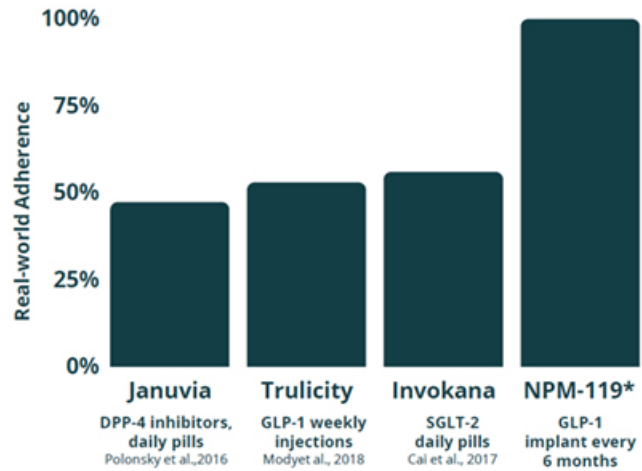
- Orals and injectables do not guarantee adherence
- Approximately 50% of patients do not meet glycemic targets primarily due to adherence

## 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.



**Guaranteed adherence is expected to deliver improved health outcomes**

Drug Substance + Administration = Drug Product

- Varying levels of adherence are associated with different health outcomes
- Different health outcomes may not be attributable to drug substance alone
- The American Diabetes Association (ADA) Standard of Care guidelines encourage treatment options that address adherence

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

Drug Substance	Administration	Drug Product
<b>exenatide</b> (GLP-1 Receptor Agonist)	Weekly Injection	<b>BYDUREON®</b>
<b>dulaglutide</b> (GLP-1 Receptor Agonist)	Weekly Injection	<b>trulicity</b> once weekly
<b>semaglutide</b> (GLP-1 Receptor Agonist)	Weekly Injection  Daily Pill	<b>OZEMPIC®</b> semaglutide injection 0.5mg/1mg <b>RYBELSUS®</b> semaglutide tablets
<b>exenatide</b> (GLP-1 Receptor Agonist)	6-Month Implant	<b>NPM-119*</b>

## Intarcia's 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\* (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 agrees to grant public hearing to Intarcia / Date for Advisory Committee pending

\* CRL: Complete Response Letter – issued by FDA to identify NDA deficiencies

## NPM-119 well-positioned to avoid Intarcia'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)



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



**NPM-119**  
**Clinical and Regulatory Pathway**

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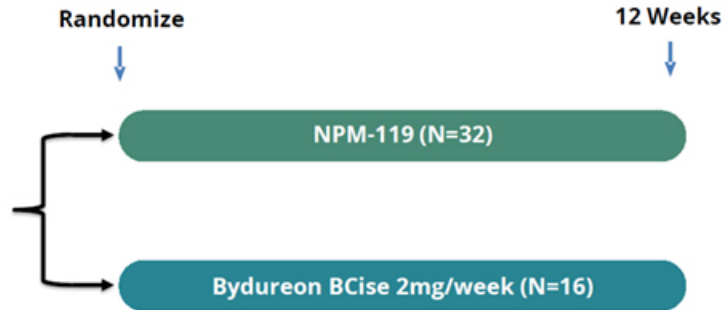
# Proposed First in Human Trial: LIBERATE-1

**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  $\geq 6.5\%$  and  $< 10.0\%$
- 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

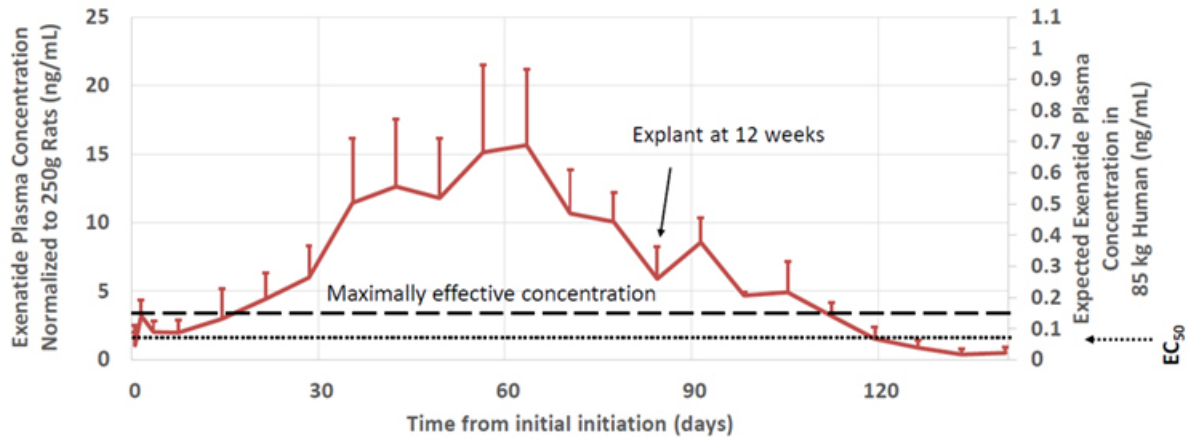
Year(s)	Milestone	Status
2020	FDA Pre-IND Meeting	Completed
Mid-2023	File IND to support Ph 2 (LIBERATE-1) clinical study	On-Track
2024	Deliver LIBERATE-1 top-line results	Projected

We expect to utilize the 505(b)(2) pathway, which permits submissions to rely, in part, on the safety and effectiveness of a previously approved product, which may potentially result in a significantly more expeditious and cost-effective pathway to FDA approval than is typically required for new diabetes therapeutics.

Progress towards IND-enabling activities:

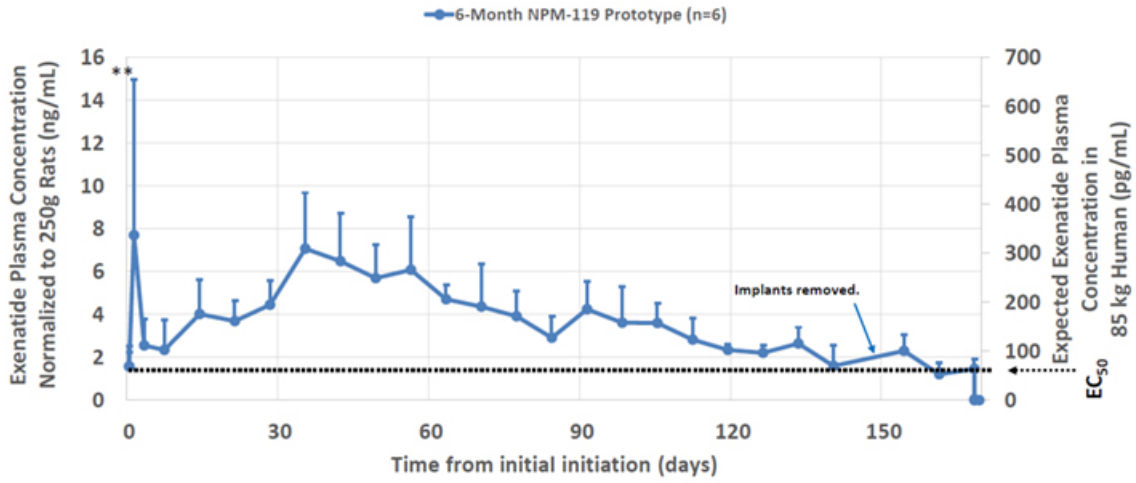
- Development of NPM-119 to be used in LIBERATE-1 is complete
- Recent extensive studies have confirmed excellent biocompatibility of NPM-119's device constituent
- NPM-119 was well tolerated in a preclinical GLP toxicology study
- IND-enabling data is complete
- GMP production of LIBERATE-1 clinical supplies is underway

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



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

# 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.





**Vivani Medical, Inc.  
Financial Information**

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# Vivani Medical, Inc.

## Q1 2023: P&L Statement

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development, net of grants	\$ 3,955	\$ 2,679
General and administrative, net of grants	2,646	1,228
Total operating expenses	<u>6,601</u>	<u>3,907</u>
Loss from operations	(6,601)	(3,907)
Other income (expense), net	283	(17)
Net loss	<u>\$ (6,318)</u>	<u>\$ (3,924)</u>
Net loss per common share – basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.11)</u>
Weighted average common shares outstanding – basic and diluted	<u>50,755</u>	<u>36,806</u>

# Vivani Medical, Inc.

## Q1 2023: Balance Sheet

Condensed and Consolidated Balance Sheet (unaudited)  
(in thousands)

	For period ended	
	Mar. 31, 2023	Dec. 31, 2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$38,073	\$45,076
Prepaid expenses and other current assets	2,611	2,452
Total current assets	\$40,684	\$47,528
Property and equipment, net	1,111	1,182
Right-of-use assets	1,148	779
Restricted cash	1,366	1,366
Deposits and other assets	271	275
Total assets	\$44,580	\$51,130
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Total current liabilities	\$5,863	\$6,822
Total liabilities	\$6,212	\$6,822
Stockholders' equity:		
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding	\$109,050	\$109,050
Addition paid-in capital and accumulated deficit	(70,682)	(64,742)
Total stockholders' equity	38,368	44,308
Total liabilities and stockholders' equity	\$44,580	\$51,130

# Vivani Medical, Inc.

## Q1 2023: Cap Table

As of March 31, 2023

Equity	WAEP*	Number of Shares
Common Stock		50,793,799
Stock Options	\$2.81	6,055,229
RSUs	\$3.15	402,500
Warrants **	\$11.13	10,310,543
Fully Diluted Shares		67,562,071

\*Weighted Average Exercise Price

\*\*Actual warrants total 15,437,918 including 7,680,938 for Second Sight which when exercised 3 for 1, convert to 2,560,313 common shares

## Vivani Medical, Inc.

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- 2 Lead program NPM-119 is a miniature, 6-month, GLP-1 implant under development for the treatment of patients with type 2 diabetes (T2D) and obesity. Our Phase 2 clinical study of NPM-119 in T2D patients, named LIBERATE-1, is on schedule to start in 2023.
- 3 In March, we announced the proposed initial public offering of our Neuromodulation Division, renamed Cortigent, Inc. This allows Vivani to focus on our drug implant business.
- 4 Vivani is well-positioned with new leadership and sufficient capital to support multiple milestones for NPM-119 and our emerging pipeline of innovative therapeutic implants.

**FOR IMMEDIATE RELEASE****Vivani Medical Reports First Quarter Financial Results and Provides Business Update**

May 15, 2023

EMERYVILLE, Calif. -- (BUSINESS WIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) (“Vivani” or the “Company”), a biopharmaceutical company developing miniaturized, long-term drug implants, including lead product NPM-119 for the treatment of patients with type 2 diabetes and/or obesity, today reported financial results for the first quarter and provided a business update. NPM-119 is a preclinical stage, 6-month, GLP-1 implant using Vivani’s proprietary NanoPortal™ implant technology.

Vivani continues to advance the development of its emerging portfolio 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.

Adam Mendelsohn, Chief Executive Officer said, “Vivani remains on schedule with the planned submission of an Investigational New Drug (IND) application for NPM-119 (GLP-1 implant) and the subsequent initiation of the proposed first-in-human Phase 2 clinical study of NPM-119, “LIBERATE-1”, in mid-2023.” Dr. Mendelsohn further commented “We believe that NPM-119 has the potential to significantly improve real-world outcomes for the approximately half of patients with type 2 diabetes who are non-adherent with their medication. We further believe that NPM-119 may also provide an improved gastrointestinal side-effect profile compared to other available GLP-1 treatment options because of NPM-119’s steady drug delivery profile.” The LIBERATE-1 trial will be the first clinical study of the company’s platform NanoPortal implant technology.

**First Quarter Business Highlights**

In January 2023, Vivani successfully completed the IND-enabling, non-clinical toxicology, and biocompatibility studies to support the planned IND submission for NPM-119 (exenatide implant) under development for the treatment of patients with type 2 diabetes. By mid-2023, we plan to file an IND with the U.S. Food and Drug Administration (the “FDA”) and, if clearance is obtained, initiate LIBERATE-1. 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 an active comparator Bydureon BCise® (exenatide extended-release injectable suspension 2mg). LIBERATE-1 will also evaluate the treatment effects on glycemic control and weight, and the inclusion of the active comparator is intended to explore the feasibility of an abbreviated 505(b)(2) approval pathway for NPM-119.

In March 2023, Vivani announced the filing of a Registration Statement on Form S-1 with the U.S. Securities and Exchange Commission (“SEC”) for the proposed initial public offering of Cortigent, Inc. (“Cortigent”). Cortigent was formed for the purpose of advancing Vivani’s neuromodulation division and is expected to continue to be controlled by Vivani after the initial public offering.

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Moving forward, Vivani will focus on its Biopharm Division and the further development of NPM-119 and its emerging pipeline of innovative, miniature, long-term drug implants to treat patients with chronic diseases and high unmet medical need. Vivani's Biopharm Division has grown to nearly 40 full-time employees. Its headquarters are located at 5858 Horton Street, Emeryville, California.

#### **Upcoming Anticipated Milestones and Events**

We expect to file the NPM-119 (GLP-1 implant) IND with the FDA and, subject to IND clearance, we intend to initiate LIBERATE-1 in Q3-2023 and expect to report top-line results in the first half of 2024.

In addition, we are seeking to complete the Initial Public Offering for our Cortigent business in the third quarter of 2023 enabling us to continue advancing our neuromodulation technology.

We will also be participating in several investor conferences and attending key industry conferences including the 2023 BIO International Convention June 5-8, 2023, in Boston MA and the American Diabetes Association 83<sup>rd</sup> Scientific Sessions June 23-26, 2023, in San Diego, CA.

#### **First Quarter 2023 Financial Results**

*Cash Balance:* As of March 31, 2023, Vivani had cash and cash equivalents totaling \$38.1 million compared to \$45.1 million as of December 31, 2022. The decrease is attributed to the \$6.3 million operating loss plus a reduction of working capital of \$1.1 million, offset partially by \$0.4 million of non-cash expenses. We believe our cash and cash equivalents as of March 31, 2023, are sufficient to fund operations into the second half of 2024.

*Research and Development Expense:* Research and development expense increased by \$1.3 million, or 48%, to \$4.0 million in the first quarter of 2023 from \$2.7 million in the first 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 costs for the quarter by \$0.6 million. The remainder of the increase was primarily due to subdermal drug implants development costs.

*General and Administrative Expense:* General and administrative expenses increased \$1.4 million, or 115%, to \$2.6 million in the first quarter of 2023 from \$1.2 million in the same period of 2022. This increase is primarily attributable to increased costs associated with the inclusion of our acquired company Second Sight which totaled \$1.1 million in the first quarter of 2023.

*Operating Expense:* Operating expenses were \$6.6 million for the three months ended March 31, 2023, compared to \$3.9 million for the three months ended March 31, 2022, representing an increase of \$2.7 million, or 69%. The inclusion of Second Sight costs for the first quarter of 2023 totaled \$1.7 million.

*Net Loss:* The net loss was \$6.3 million as compared to \$3.9 million for the three-months ended March 31, 2023, and 2022, respectively. The \$2.4 million increase in net loss was primarily attributable to a \$2.7 million increase in operating expenses, as noted above, partially offset by an increase of \$0.3 million in interest income due to our higher cash balance.

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## 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 tolerance to their medication. Vivani's lead program NPM-119 is a miniaturized, 6-month GLP-1 implant under investigation for the treatment of patients with type 2 diabetes and/or obesity. NPM-119 is 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 US alone, is a primary and daunting reason why type 2 diabetes treatments face significant challenges in achieving positive real-world effectiveness.

Vivani's wholly owned subsidiary Cortigent, Inc., has developed, manufactured, and marketed implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. Cortigent continues to assess strategic options for advancing its pioneering neuromodulation technology including the Orion® Visual Cortical Prosthesis System for providing artificial vision to profoundly blind individuals and a new medical device system to improve the recovery of hand and arm movement in partially paralyzed stroke patients undergoing rehabilitation.

## 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 and the planned development therefor, 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; delays and changes in applicable laws, regulations and guidelines including potential delays in submitting required regulatory applications to the U.S. Food and Drug Administration ("FDA"); 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 Securities and Exchange Commission (the "Commission") filed on March 31, 2023. 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)

	March 31, 2023	December 31, 2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 38,073	\$ 45,076
Prepaid expenses and other current assets	2,611	2,452
Total current assets	40,684	47,528
Property and equipment, net	1,111	1,182
Right-of-use assets	1,148	779
Restricted cash	1,366	1,366
Deposits and other assets	271	275
Total assets	<u>\$ 44,580</u>	<u>\$ 51,130</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 746	\$ 1,177
Accrued expenses	2,114	2,358
Litigation accrual	1,675	1,675
Accrued compensation expense	415	657
Current operating lease liabilities	913	955
Total current liabilities	5,863	6,822
Long term operating lease liabilities	349	—
Total liabilities	6,212	6,822
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding: 50,789 as of March 31, 2023 and 50,736 as of December 31, 2022, respectively	109,050	109,050
Additional paid-in capital	8,378	8,009
Accumulated other comprehensive loss	44	35
Accumulated deficit	(79,104)	(72,786)
Total stockholders' equity	38,368	44,308
Total liabilities and stockholders' equity	<u>\$ 44,580</u>	<u>\$ 51,130</u>

VIVANI MEDICAL, INC.  
AND SUBSIDIARIES

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

	Three Months Ended	
	March 31,	
	2023	2022
Operating expenses:		
Research and development, net of grants	\$ 3,955	\$ 2,679
General and administrative, net of grants	2,646	1,228
Total operating expenses	6,601	3,907
Loss from operations	(6,601)	(3,907)
Other income (expense), net	283	(17)
Net loss	\$ (6,318)	\$ (3,924)
Net loss per common share – basic and diluted	\$ (0.12)	\$ (0.11)
Weighted average common shares outstanding – basic and diluted	50,755	36,806