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): September 15, 2023

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

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

1350 South Loop Road **Alameda, CA** (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 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**

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. This updated slide deck provides an update on the regulatory status of NPM-119 (GLP-1 implant) currently under development for the treatment of patients with type 2 diabetes. As previously reported the original Investigational New Drug Application ("IND") for NPM-119 was filed with the U.S. Food and Drug Administration ("FDA") on July 14, 2023, to support the initiation of the Phase 2a, first in human study of NPM-119 in patients with type 2 diabetes, also named LIBERATE-1. On August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on Full Clinical Hold pending the resolution of Chemistry, Manufacturing and Controls ("CMC") information related to the assessment of device risks and device performance. On August 25, 2023, Vivani provided a Complete Response ("CR") including additional information and on September 8, 2023, FDA provided an "Incomplete Response to Clinical Hold" notification indicating the responses to the CMC deficiencies were incomplete. Subsequently, Vivani submitted a second CR on September 15, 2023. Per guidelines, FDA has 30 days after the submission date to respond. Vivani will continue to work with FDA to address all outstanding deficiencies to enable lifting of the Clinical Hold and initiation of the proposed LIBERATE-1 study as soon as possible. Regarding guidance, if the CR is adequate and the Clinical Hold is lifted, Vivani anticipates commencing LIBERATE-1 in 2023, interim results (full 12-week data from the first ~12 patients) in 1H2024, and full top-line results in 2H2024. If the CR is deemed inadequate, Vivani will provide updated guidance as appropriate. While the Company has elected to update the corporate slide presentation in parallel with this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so in the future.

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 September 18, 2023.
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: September 18, 2023

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

Exhibit 99.1


Vivani
Nasdaq: VANI
www.vivani.com
Vivani Medical, Inc.
Guaranteed Adherence. Better Outcomes.
September 18, 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 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 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 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 NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability.

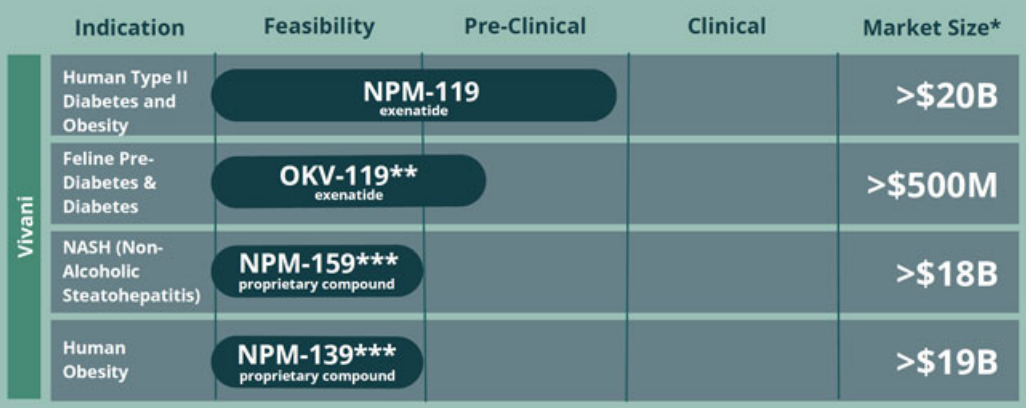
2. Lead program NPM-119 is a miniature, 6-month, GLP-1 implant under development for the treatment of patients with type 2 diabetes (T2D) and obesity. Vivani's First In Human Phase 2 study of NPM-119 in T2D patients, named LIBERATE-1, was placed on Clinical Hold prior to initiating the study. A second Complete Response to the Clinical Hold was submitted on September 15, 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



* 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

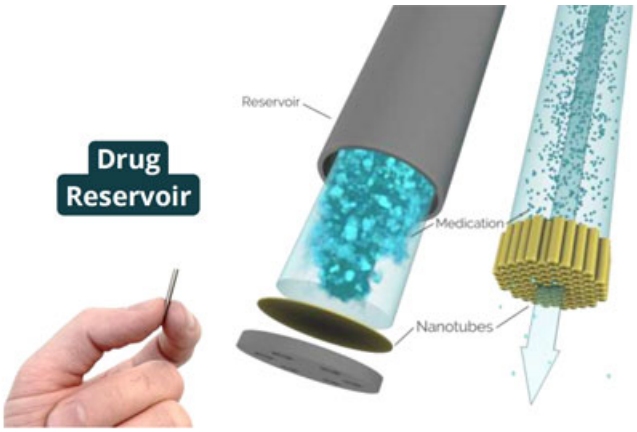
NanoPortal:

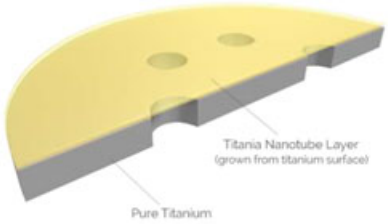
Innovative Delivery Technology

Designed to Assure Adherence

Minimally-fluctuating and tunable delivery profiles

Potential application with many molecular types



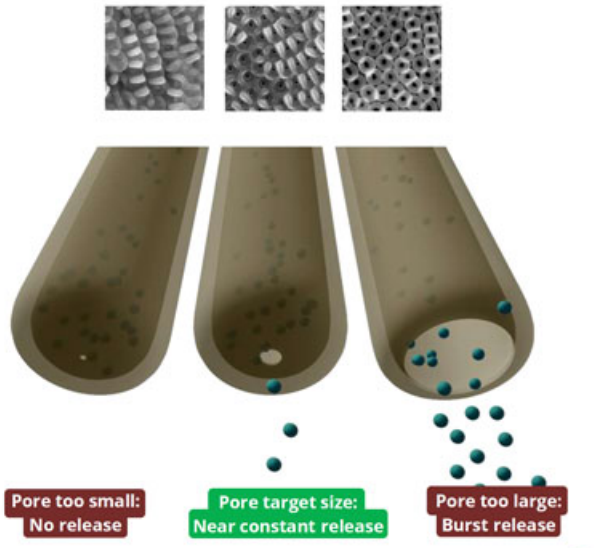


Nanotube Membrane

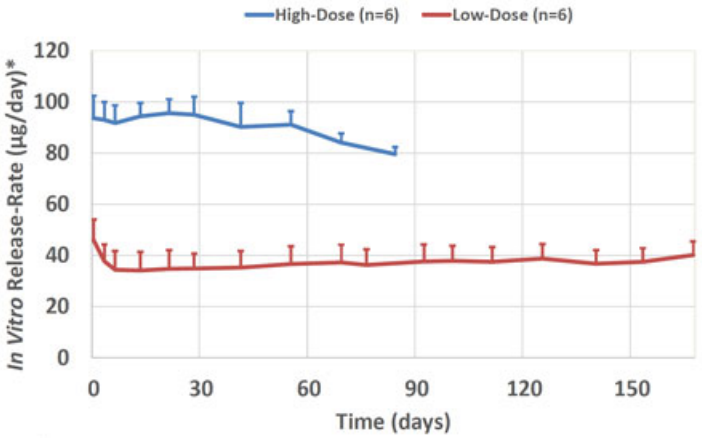
NanoPortal:

How it Works...

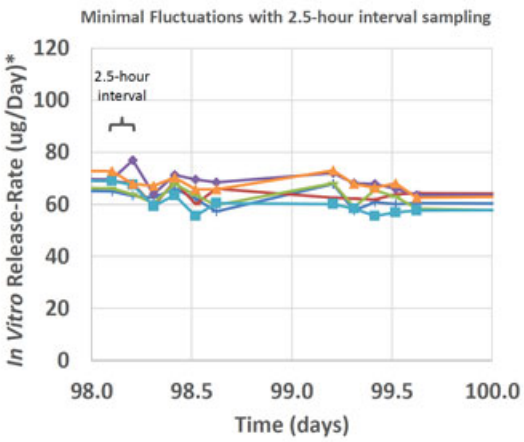
By precisely adjusting nanotubes to molecule size, interactions between drug and nanotube walls can result in desirable release profiles over time, including **near constant release**



Near-Constant and Minimally-Fluctuating Release



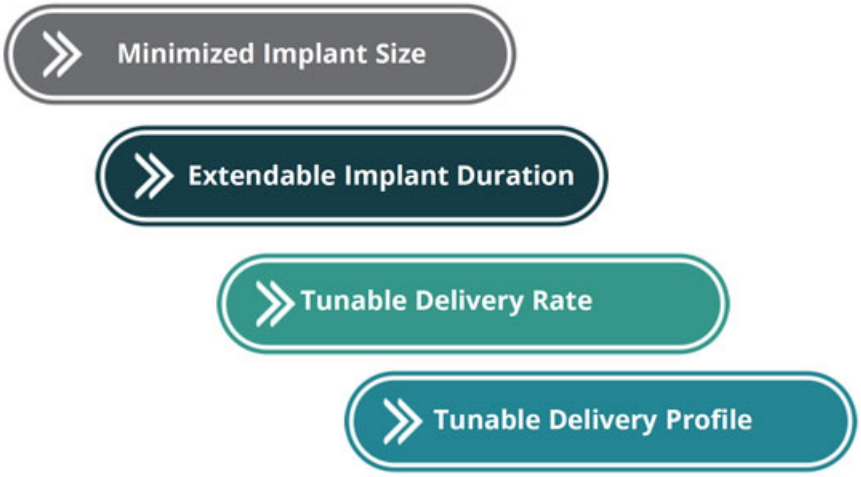
*Release-rates include exenatide and related substances. Day 1 timepoint includes cumulative release over the first day including a separately measured 1st hour of release, which was ~7 µg for the high-dose and ~4 µg for the low-dose.



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
>$20B in 2022 & >$35B Expected in 2028

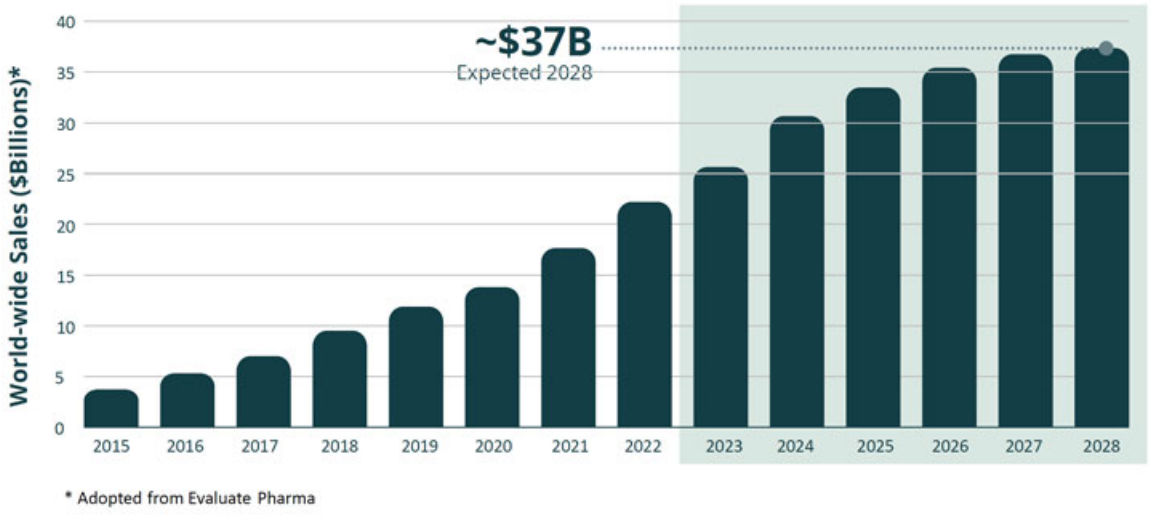
Lead Product (NPM-119):

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

- 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

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

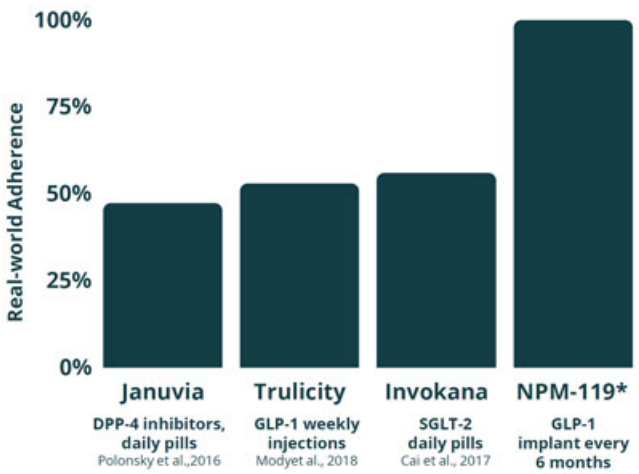
- Orals and injectables do not guarantee adherence
- Approximately 50% of patients do not meet glycemic targets primarily due to adherence

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
exenatide (GLP-1 Receptor Agonist)	Weekly Injection	BYDUREON®
dulaglutide (GLP-1 Receptor Agonist)	Weekly Injection	once weekly trulicity®
semaglutide (GLP-1 Receptor Agonist)	Weekly Injection	OZEMPIC® semaglutide injection 0.5mg 1mg
	Daily Pill	RYBELSUS® semaglutide tablets
exenatide (GLP-1 Receptor Agonist)	6-Month Implant	NPM-119*

i2o Therapeutic'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 to discuss i2o's ITCA-650 scheduled for September 21, 2023

[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 i2o'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

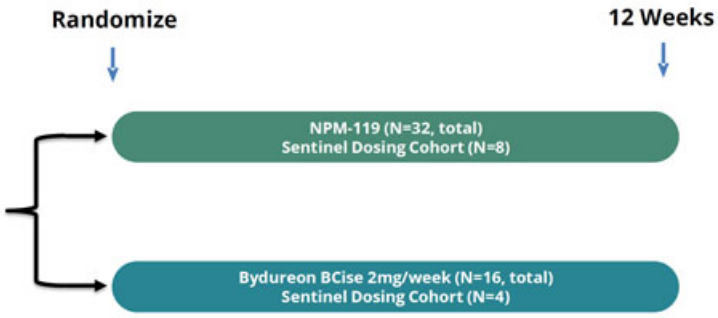
Proposed First in Human Trial: LIBERATE-1

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 <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



Preliminary Data - First 4 weeks of sentinel dosing cohort (n=12), reviewed by FDA before enrollment continues
Interim Data - Full 12 weeks of sentinel dosing cohort (n=12)
Top-Line Data - Full 12 weeks for all patients (n=32)

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

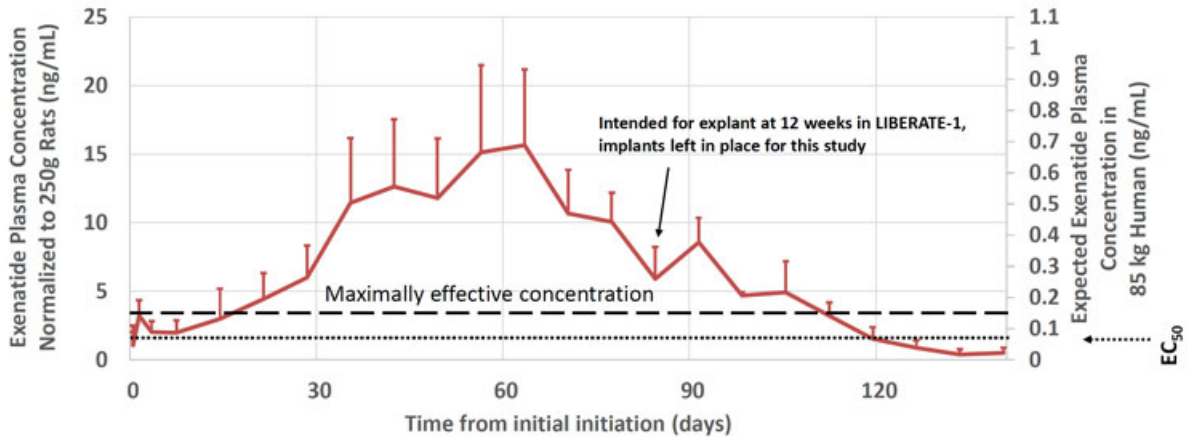
Year(s)	Milestone	Status
2023	IND filed to support Ph 2a (LIBERATE-1) clinical study	July 14, 2023
2023	FDA provided Clinical Hold letter and CMC deficiencies	August 18, 2023
2023	Vivani submitted second Complete Response to Clinical Hold	September 15, 2023

August 18, 2023 – FDA provided written notification of a Clinical Hold on the proposed LIBERATE-1 study 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.

September 15, 2023 – Vivani provided a second Complete Response (CR) including additional information and commitments to obtain supplemental information in parallel with the conduct of LIBERATE-1. Per guidelines, FDA has 30 days after the submission date to respond.

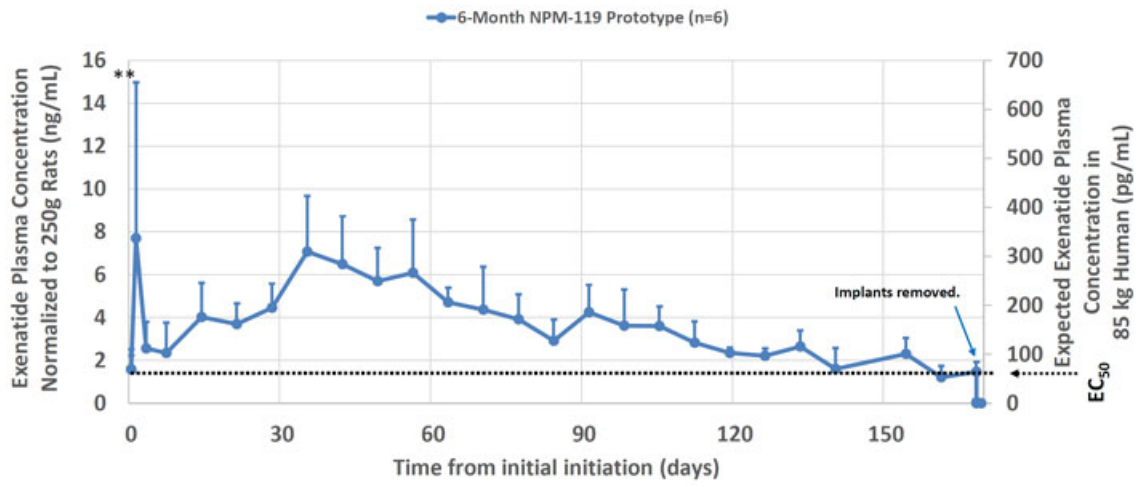
- If the CR is adequate and the Clinical Hold is lifted, Vivani anticipates commencing LIBERATE-1 in 2023, preliminary results in 1Q2024, interim results in 1H2024, and top-line results 2H2024.
- If the CR is deemed inadequate, Vivani will provide updated guidance as appropriate.

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

Vivani Medical, Inc.
Q2 2023: P&L Statement

Condensed Consolidated Statements of Operations (unaudited)

In Thousands, except Share Data	3 Months Ended Jun. 30, 2023	3 Months Ended Jun. 30, 2022	6 Months Ended Jun. 30, 2023	6 Months Ended Jun. 30, 2022
Operating expenses:				
Research and development, net of grants	3,864	3,203	7,819	5,883
General and administrative	3,139	884	5,785	2,112
Total operating expenses	7,003	4,087	13,604	7,995
Loss from operations	**(7,003)**	**(4,087)**	**(13,604)**	**(7,995)**
Other income (expense), net	477	(16)	760	(33)
Net income/(loss)	**$ (6,526)**	**$ (4,103)**	**$ (12,844)**	**$ (8,028)**
Net income/(loss) per common share – basic	**$ (0.13)**	**$ (0.11)**	**$ (0.25)**	**$ (0.22)**
Weighted average common shares outstanding – basic	**50,795**	**36,880**	**50,748**	**36,819**

Vivani Medical, Inc.
Q2 2023: Balance Sheet

Statement - Condensed Consolidated Balance Sheets (unaudited)

In Thousands	Jun. 30, 2023	Dec. 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,486	$ 45,076
Prepaid expenses and other current assets	3,669	2,452
Total current assets	36,155	47,528
Property and equipment, net	1,142	1,182
Right-of-use assets	20,684	779
Restricted cash	1,366	1,366
Deposits and other assets	260	275
Total assets	**$ 59,607**	**$ 51,130**
LIABILITIE S AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 7,086	$ 6,822
Long term operating lease liabilities	20,127	—
Total liabilities	**27,213**	**6,822**
Stockholders' equity:		
Total Common Stock, APIC & Other Comp Loss	118,024	117,094
Accumulated deficit	(85,630)	(72,786)
Total liabilities and stockholders' equity	**$ 59,607**	**$ 51,130**

Vivani Medical, Inc.
Q2 2023: Cap Table

As June 30, 2023

Equity	WAEP*	Number of Shares
Common Stock		50,798,799
Stock Options	$2.79	6,139,233
RSUs	$3.15	402,500
Warrants **	$11.13	10,310,543
Fully Diluted Shares		67,651,075

**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*

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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.