



Nasdaq: VANI

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

# Vivani Medical, Inc.

*Guaranteed Adherence. Better Outcomes.*

# Disclaimers

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# Vivani Executive Leadership Team



## Adam Mendelsohn PhD – CEO/Director

- Co-founder/Co-inventor of Vivani technology
- PhD Bioengineering (UCSF/UC Berkeley)
- Management of Technology Certificate at Haas School of Business
- Research focused on diabetes treatment
- Formerly at Boston Scientific and Minimed



## Donald Dwyer, MBA – Chief Business Officer

- Former Executive Director at AstraZeneca with leadership roles in regulatory affairs, drug development, commercial and business development
- Former Vivani Board observer for AZ
- Former PhaseBio Board observer for AZ (prior to IPO)
- Former Director at Cephalon and Rhone Poulenc Rorer



## Lisa Porter, MD – Chief Medical Officer

- Former Chief Medical Officer for Eiger BioPharmaceuticals and Dance BioPharm
- Former VP of Medical Development for Amylin
- Former Director at GSK, Global Head of Clinical Strategy for Avandia
- Former Board member of ViaCyte, Inc.



## Truc Le, MBA – Chief Operations Officer

- Numerous COO and Executive Positions at Device and Drug-Device Companies, including:
- CTO at Dance Biopharm, COO at Avid Bio
- Exec VP at Prima Biomed, Sr. VP at Nektar Therapeutics (responsible for Exubera approval), and Worldwide VP at Johnson & Johnson



## Brigid A. Makes, MBA – Chief Financial Officer

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

# Vivani Medical, Inc.

- 1** An innovative, biopharmaceutical company developing a portfolio of ultra long-acting, miniature, drug implants to treat chronic diseases. NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability.
- 2** Lead program NPM-115 is a miniature, six-month, GLP-1 (high-dose exenatide) implant under development for chronic weight management in obese or overweight patients.
- 3** Pipeline includes NPM-119 which is an IND-cleared miniature, six-month, GLP-1 (exenatide) implant under development for type 2 diabetes and NPM-139 (semaglutide implant), under development for chronic weight management with the potential benefit of once-yearly dosing.
- 4** Vivani is well-positioned to advance NPM-115 and its pipeline towards potentially transformational milestones in 2024 and 2025.

# Company Pipeline

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

	Indication	Feasibility	Pre-Clinical	Clinical	Market Size*
Vivani	Human Obesity	<b>NPM-115</b> high-dose exenatide			>\$60B
	Human Type 2 Diabetes	<b>NPM-119</b> exenatide			>\$60B
	Human Obesity	<b>NPM-139</b> semaglutide			>\$60B
	Feline Pre-Diabetes & Diabetes	<b>OKV-119**</b> exenatide			>\$0.5B

\* Estimated Market Sizes where Vivani products would compete, if approved. Does not represent future sales or revenue estimates of Vivani pipeline products. Evaluate Pharma's "World Preview 2024: Pharma's Growth Burst July 2024" estimates \$130B in GLP-1 sales by 2030. We assume >\$60B for Obesity/Chronic Weight Management and >\$60B for Type 2 Diabetes by 2030.

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

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



# NanoPortal™:

## Innovative Delivery Technology



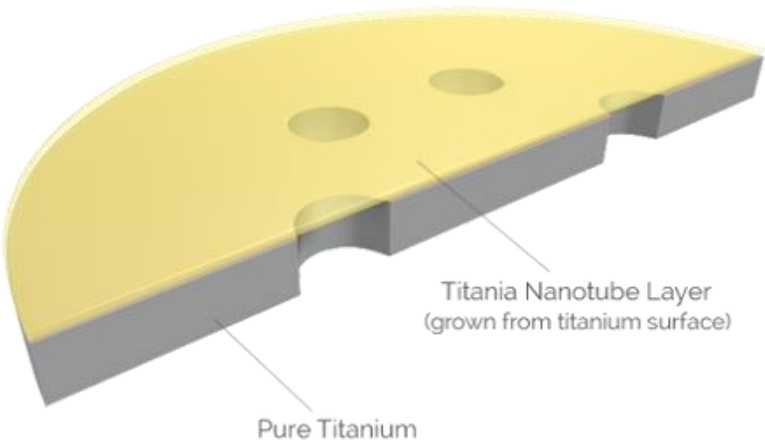
Designed to assure adherence



Minimally-fluctuating and tunable delivery profiles



Potential application with many molecular types

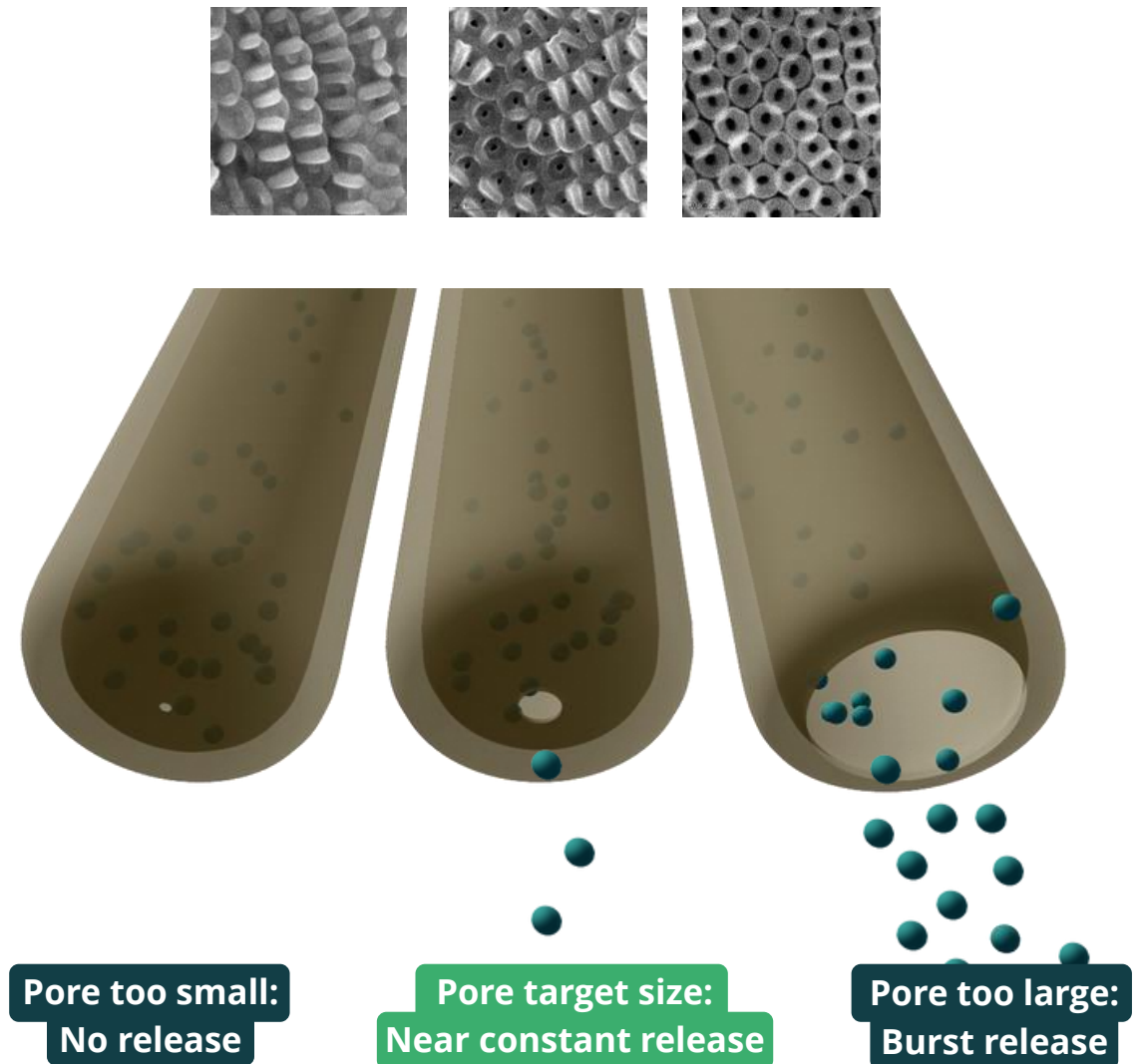


**Nanotube Membrane**

# NanoPortal™:

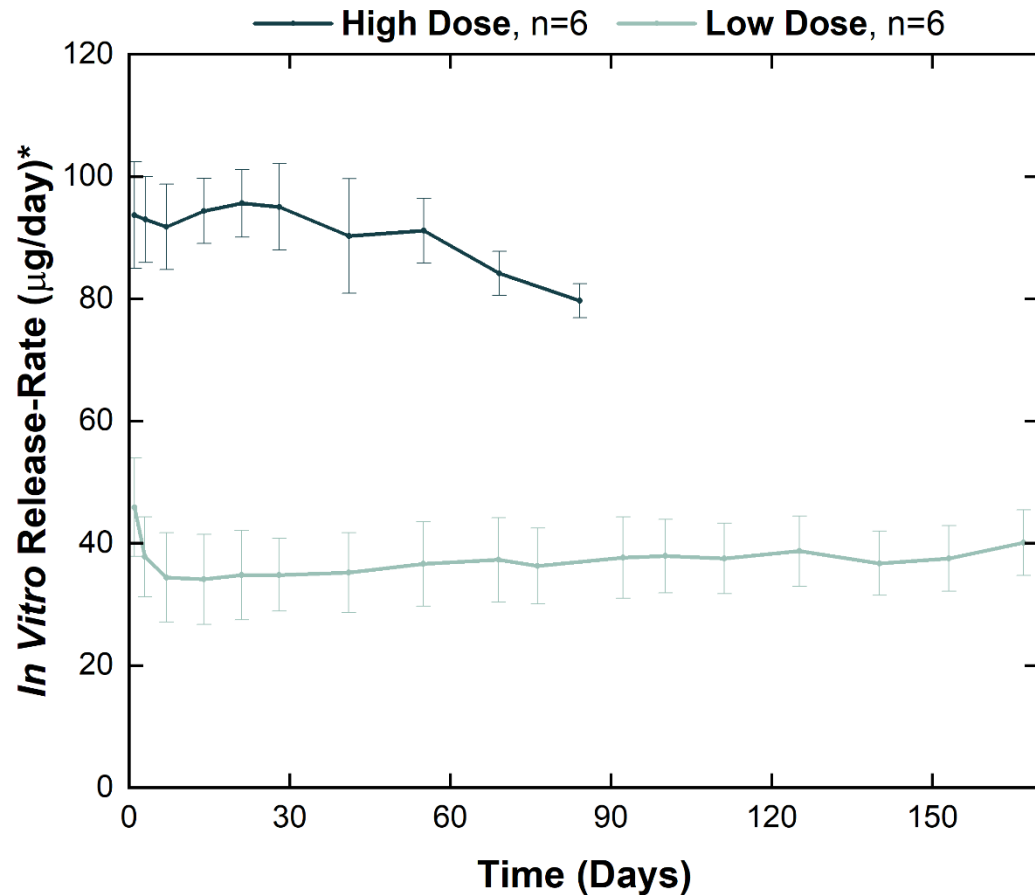
## How it Works...

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**

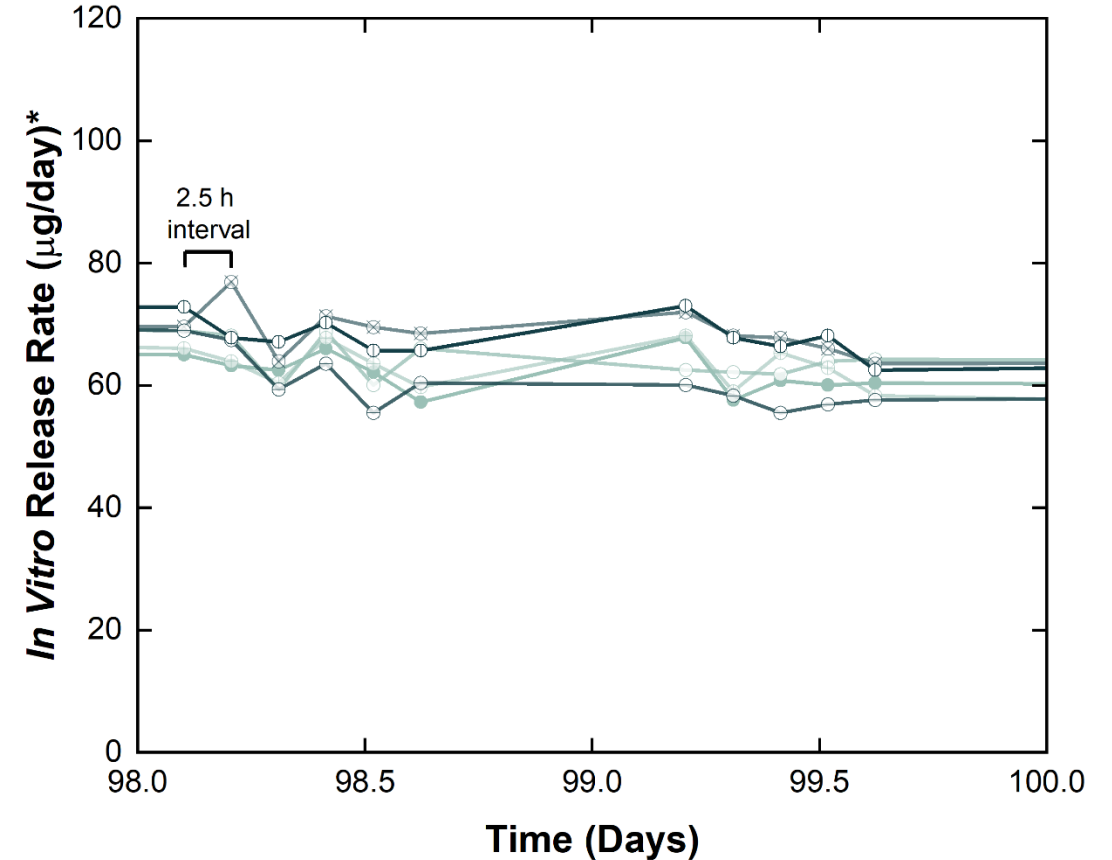




# Near-constant and minimally-fluctuating release



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



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. Values are mean ± SD.

\*Release-rates include exenatide and related substances.

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 Lead Program**

## **NPM-115**

**High-Dose Exenatide Implant for Chronic Weight Management**

**Targeting the Rapidly Growing GLP-1 RA Market**

# Lead Product NPM-115: 6-Month Exenatide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Chronic Weight Management in Obese or Overweight Patients

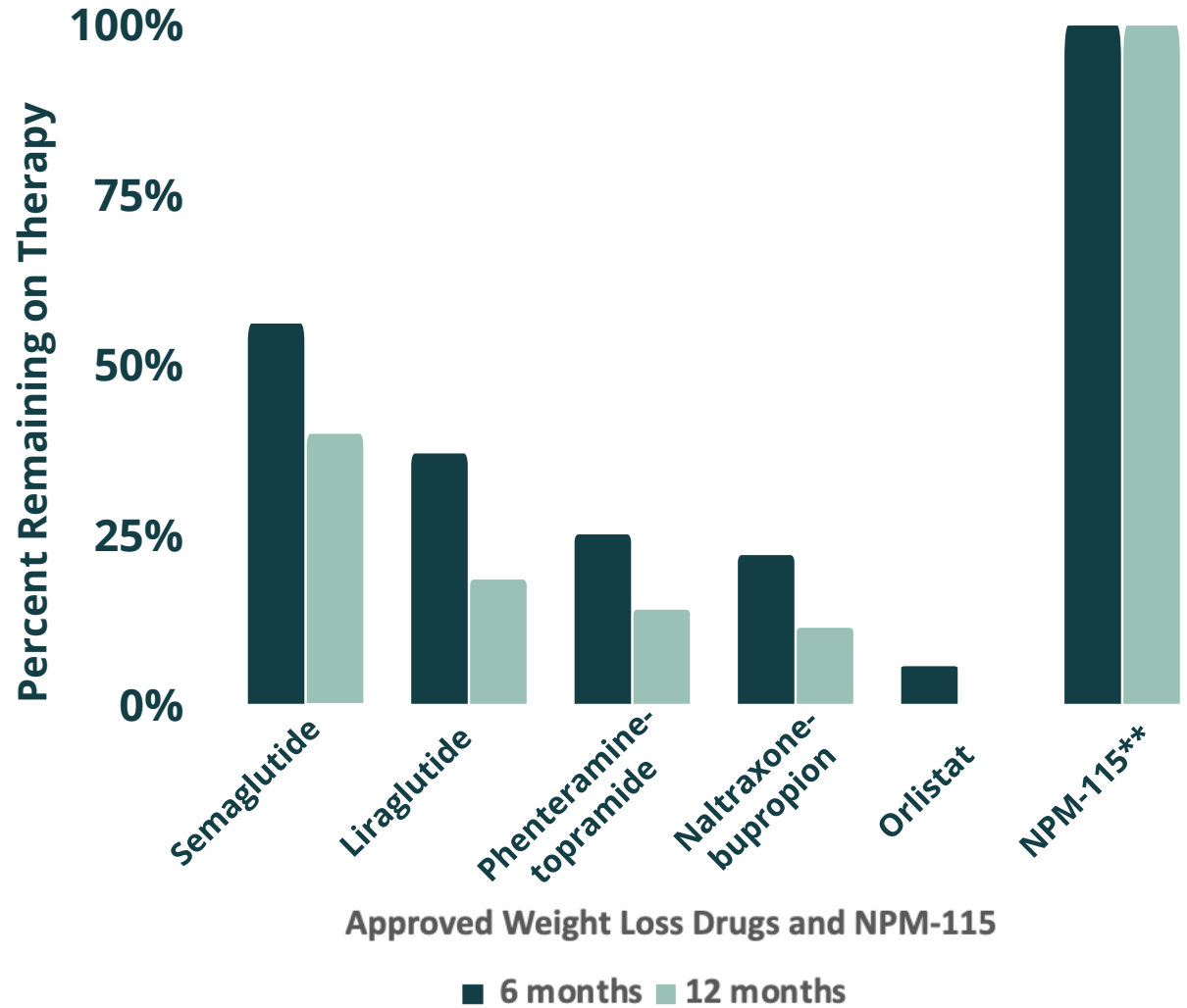
- Tremendous unmet medical need in Obesity<sup>1</sup>:
  - 764M people living with obesity
  - 15M (2%) taking an anti-obesity medication
- GLP-1 monotherapy may provide adequate weight loss for the majority of patients<sup>2</sup>
- Preclinical data with NPM-115 has demonstrated similar magnitude of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

# Weight Loss Medicines Associated With Adherence Challenges

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

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

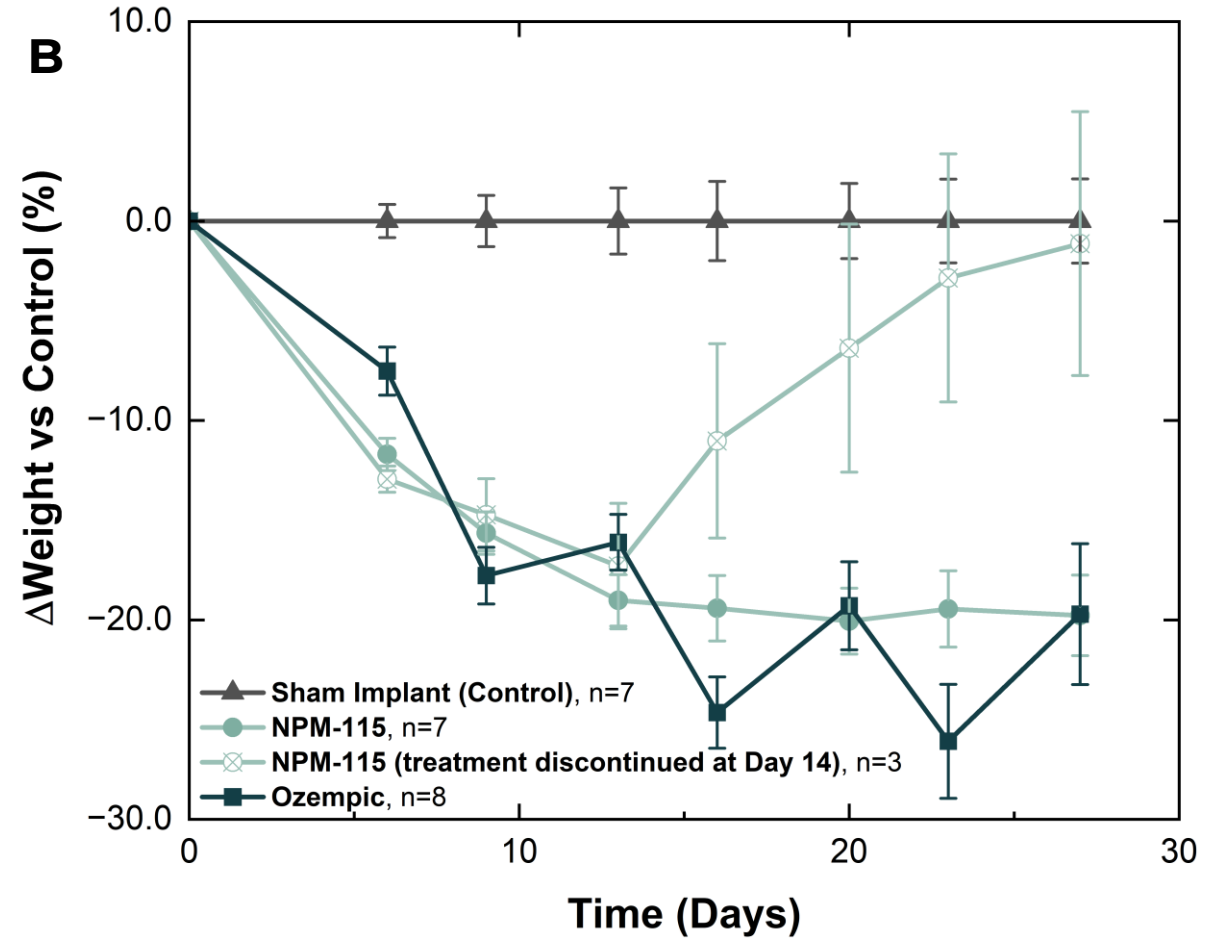
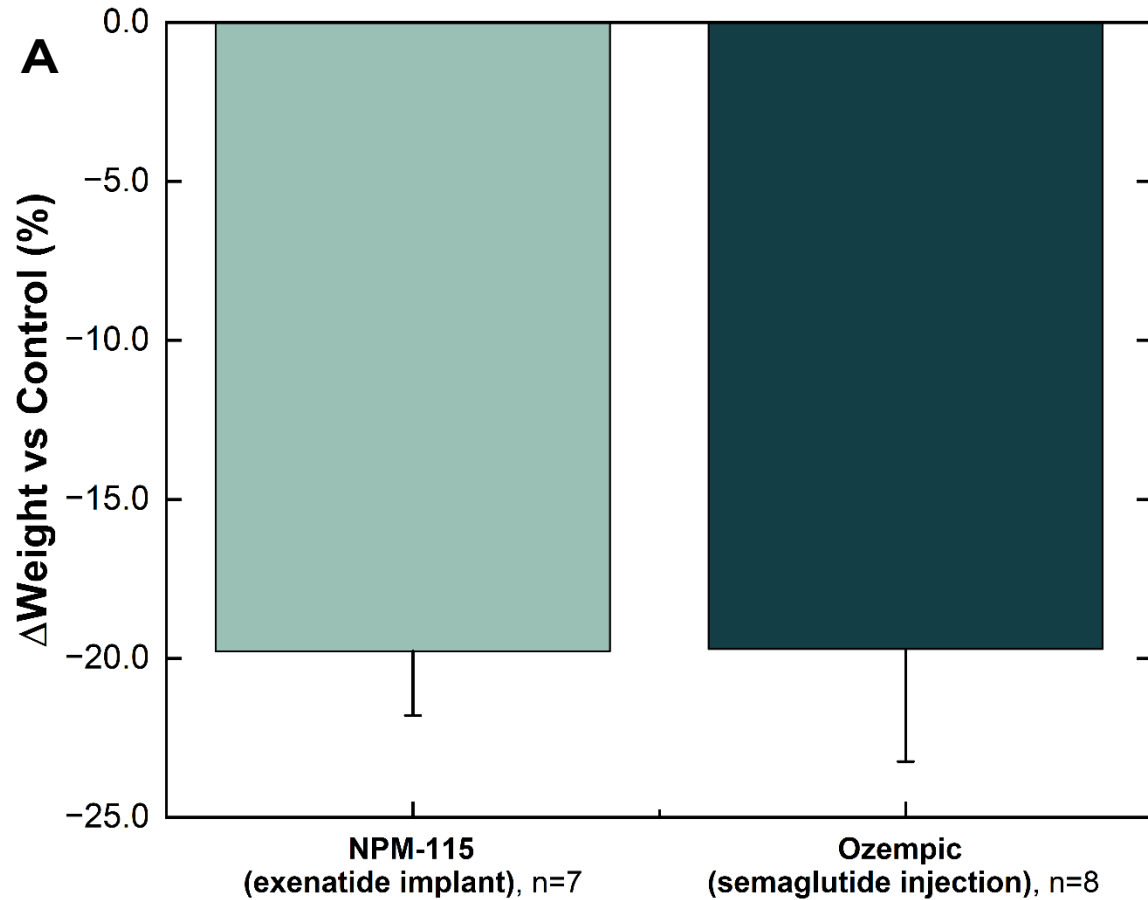
Large Retrospective Cohort Study\* (N=1,911)



\* Published in Obesity, December 8, 2023

\*\* NPM-115 (exenatide implant) was not included in the published study, assumes one implant replaced after six months. Currently under development, designed to enable 100% adherence, not approved in any market.

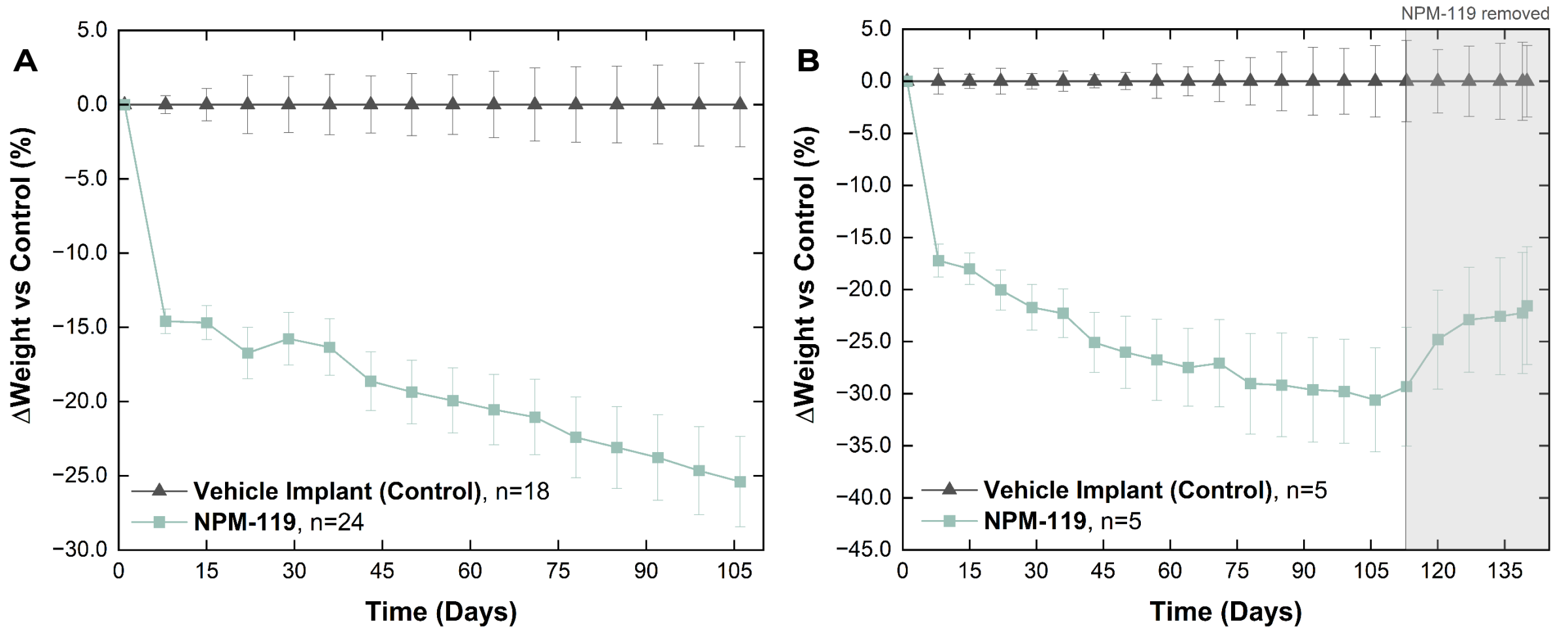
# NPM-115 associated with comparable weight loss to semaglutide in preclinical study



**Weight loss in high fat diet-induced obese mice. (A)** % weight change from baseline for a single administration of NPM-115 (exenatide, ~530 nmol/kg/day) vs weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant) at 28 days; **(B)** % weight change from baseline over time from a single administration of NPM-115 (exenatide, ~530 nmol/kg/day) vs. weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant). Values are mean  $\pm$  SE.



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

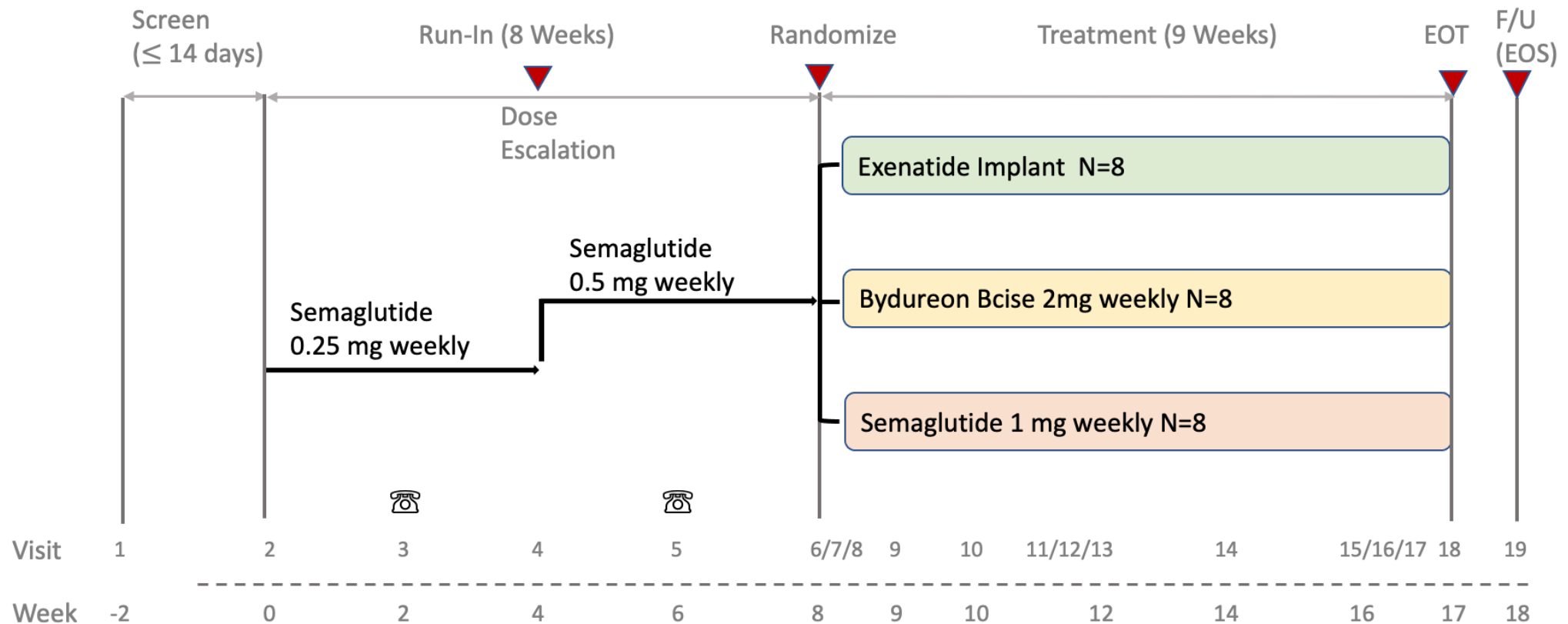


**Weight difference from control in healthy Sprague-Dawley Rats.** % weight change from baseline for a single administration of NPM-119 (exenatide, ~320 nmol/kg/day) corrected to control (vehicle implant). **(A)** All animals measured through 105 days of treatment; **(B)** 5 animals measured in each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

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

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

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



# NPM-115 Clinical + Regulatory Development

## Near-Term Plan

Year(s)	Milestone	Status
2023	Announced Designation of NPM-115 (high dose exenatide)	November 2023
2024	Reported Positive Weight Loss in Preclinical Study	February 2024
2024	Submit Application to Human Research Ethics Committee to Study Exenatide Implant in Obese and Overweight Patients	Expected 3Q2024
2024	Initiate First-In-Human Study in Obese and Overweight Patients	Expected 4Q2024
2025	Results of LIBERATE-1 available	Expected 2025

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

February 2024 – Company reported positive preclinical study results demonstrating comparable weight loss between NPM-115 implant and Ozempic/Wegovy (semaglutide injection) and a strategic shift to focus on obesity and chronic weight management.

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

**NPM-119**

**Exenatide Implant for Type 2 Diabetes**

**Targeting the Rapidly Growing GLP-1 RA Market**

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

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

<sup>1</sup> 2023 Novo Nordisk Annual Report

<sup>2</sup> Guo 2016

<sup>2,3</sup> Carls et al., 2017

<sup>4</sup> IMS 2013 Report

# NPM-119 Implant and Applicator





# Current Drug Adherence Challenge

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

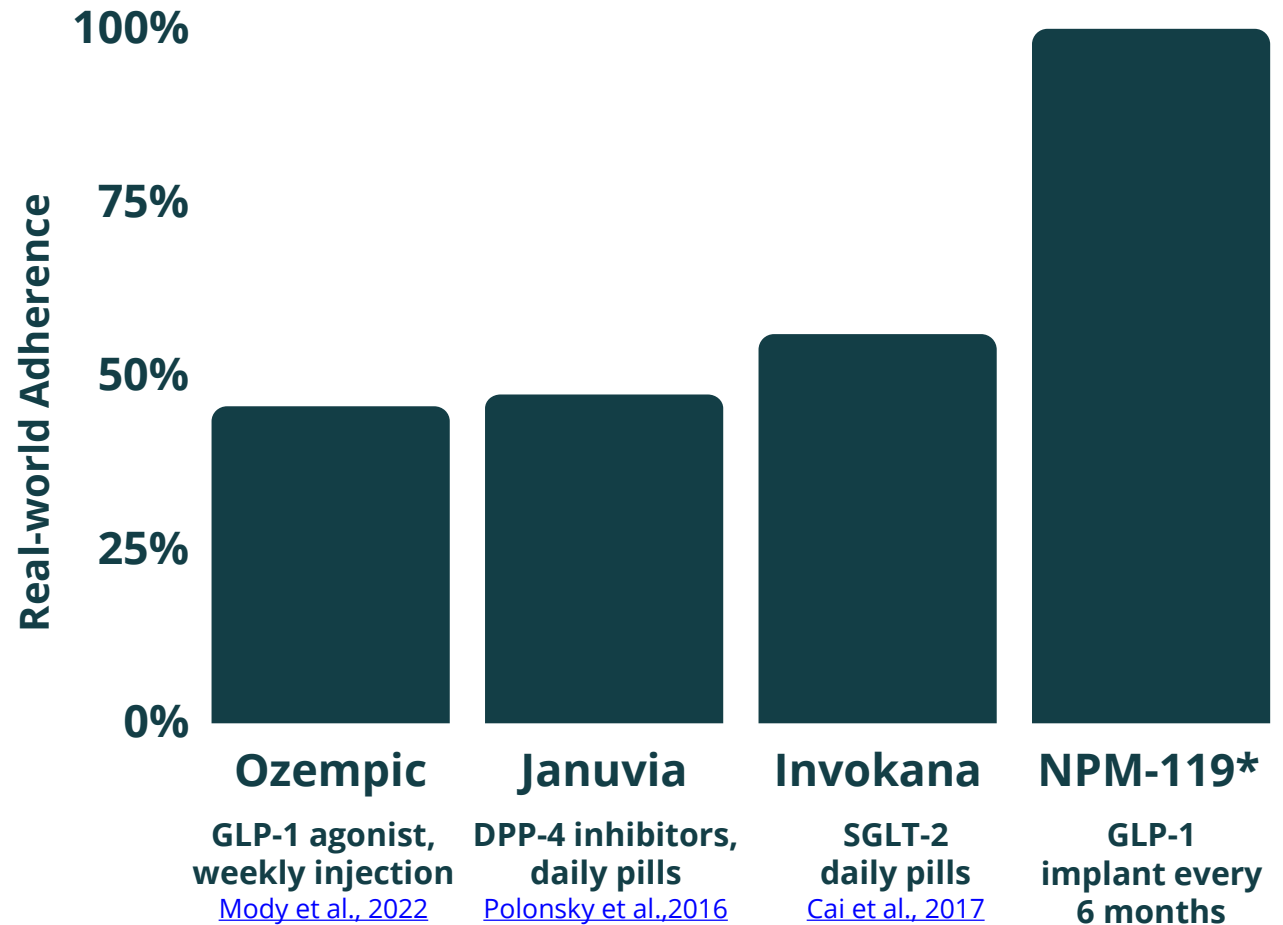
## NPM-119\* Designed to Enable 100% Adherence through Implant Duration

- 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

## Real-World Adherence of Select Drugs



\* NPM-119 – under development, designed to enable 100% adherence, not approved in any market

# Intarcia's<sup>1</sup> 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

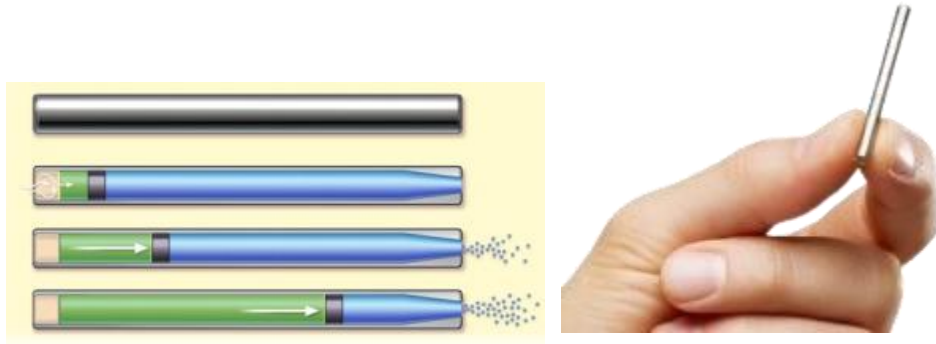
- 2014** – Intarcia signed ITCA 650 deal with Servier (excluding US + Japan) \$171M up-front, \$880M milestones, and double-digit royalties
  - Financings valued Intarcia as high as \$4.0B (2017); Intarcia's lead program was ITCA 650
- 2016** – Intarcia filed initial ITCA 650 New Drug Application (NDA)
- 2017** – FDA issued the first ITCA 650 CRL<sup>2</sup> (cited manufacturing concerns)
- 2020** – FDA issued second ITCA 650 CRL (cited clinical safety and device constituent concerns)
- 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

<sup>1</sup> i2o Therapeutics acquired Intarcia Therapeutic's assets including ITCA-650

<sup>2</sup> CRL: Complete Response Letter – issued by FDA to identify NDA deficiencies

# NanoPortal is well-positioned to avoid ITCA 650's device technology challenges

## Osmotic Pump (Intarcia)



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

## NanoPortal™ (NPM-119)

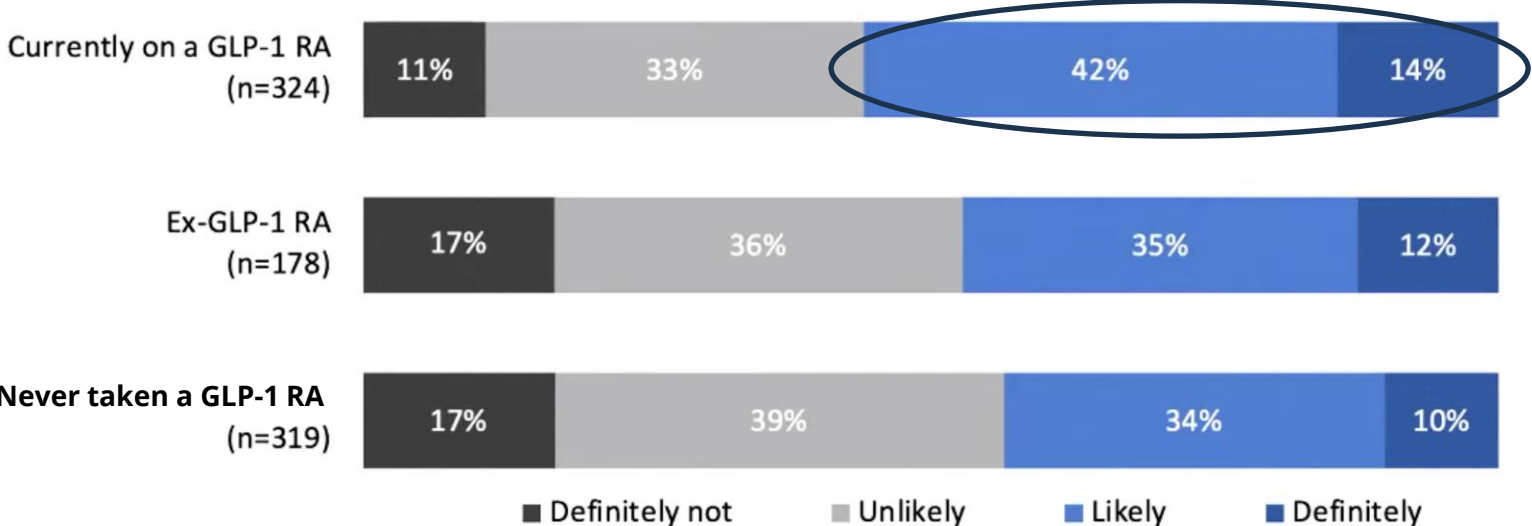


- **Minimally fluctuating drug release** profile observed in pre-clinical studies
- **Smaller Device** (2.2mm x 21.5mm)
- Insertion using **smaller 11-gauge needle**

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

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

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



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

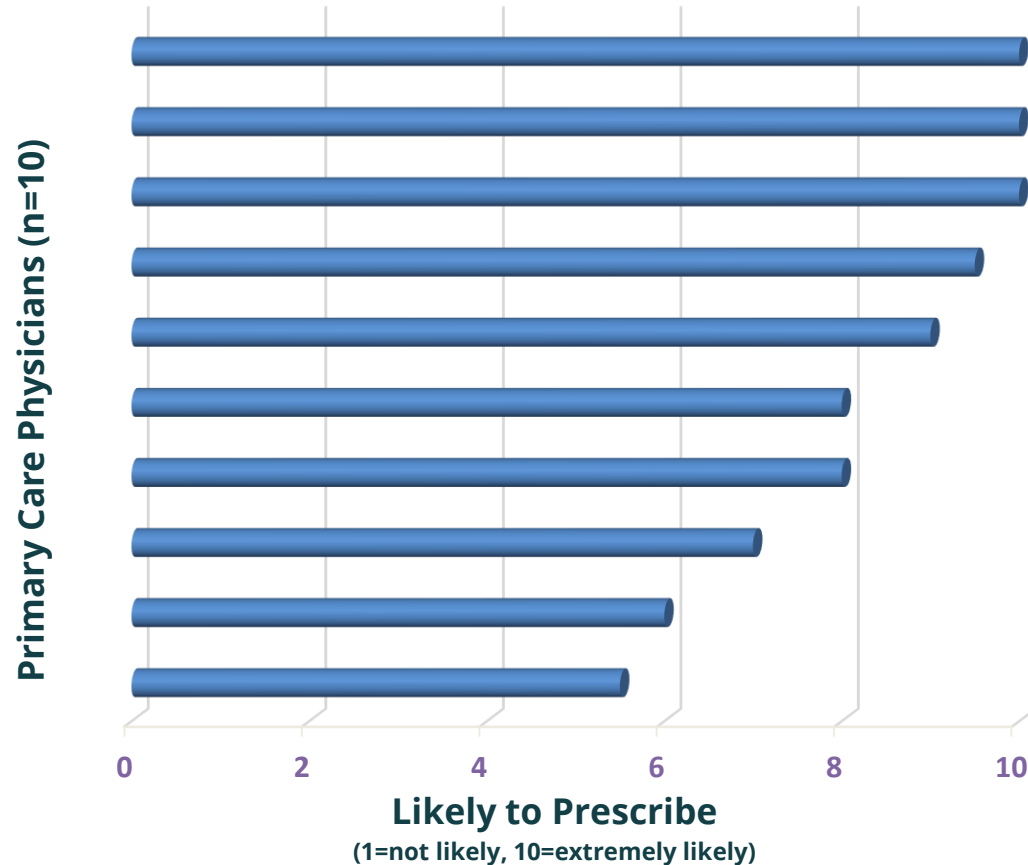
Our question, after showing an image of the device and a description\* of how it would be used, was: “Assuming it was approved by the FDA, your doctor suggests it, and insurance coverage is not an issue, how likely would you be to get and use the implant with exenatide?”



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

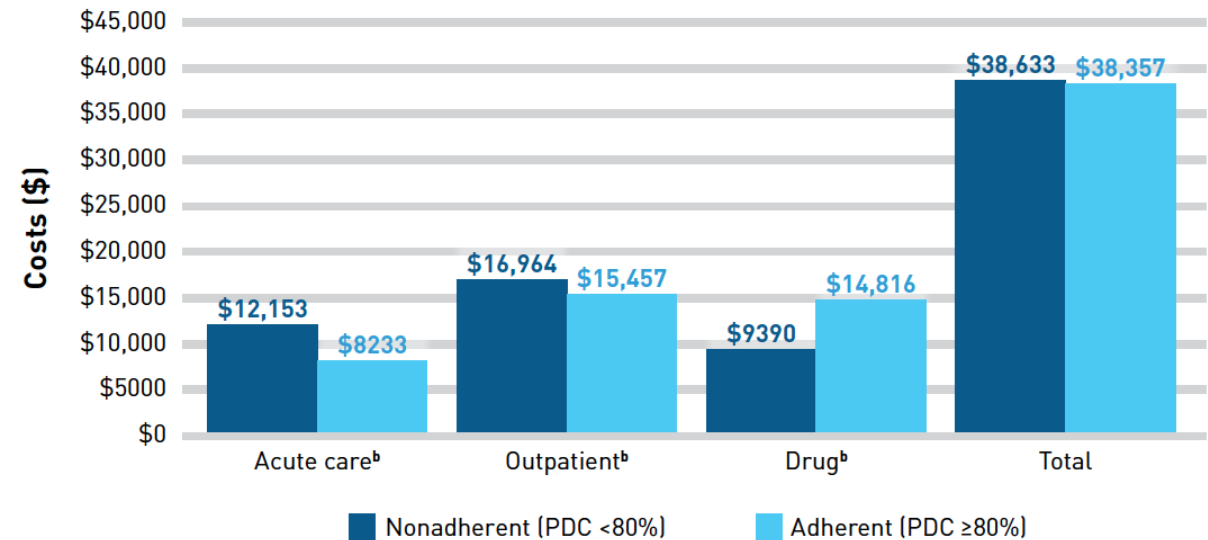
## Prescribing Rating, Average 8.3 out of 10

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



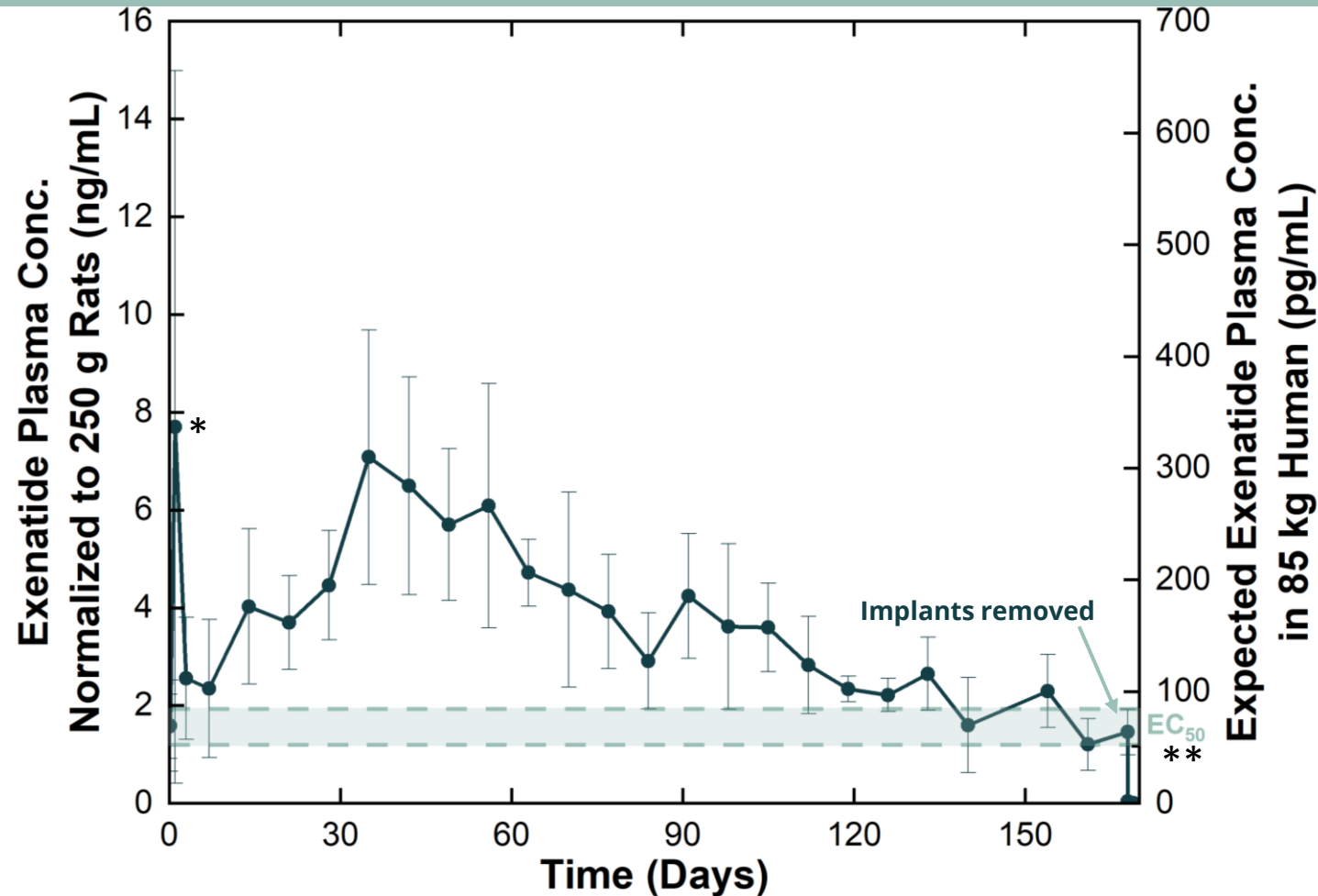
## Adherence = Lower Acute Care & Outpatient Costs

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



[Curtis et al., 2017](#)

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



## Pharmacokinetics of 6-month exenatide implant in male Sprague-Dawley rats (n=6)

Exenatide antibody-positive animals are not included in this data set. Values are mean  $\pm$  SD.

\*2 of 6 implants are responsible for higher Day 1 exenatide concentrations which is not expected to occur in the configuration to be used in the clinic.

\*\* The estimated exenatide EC50 is 51.4 pg/mL when exenatide antibody titers are < 125 and 84 pg/mL when exenatide antibody titers are  $\geq$  125. These exenatide EC50 estimates are consistent with the exenatide EC50 estimate, 83.5 pg/mL, from the FDA Clinical Pharmacology review of BYDUREON



# NPM-119 Clinical + Regulatory Development Near-Term Plan

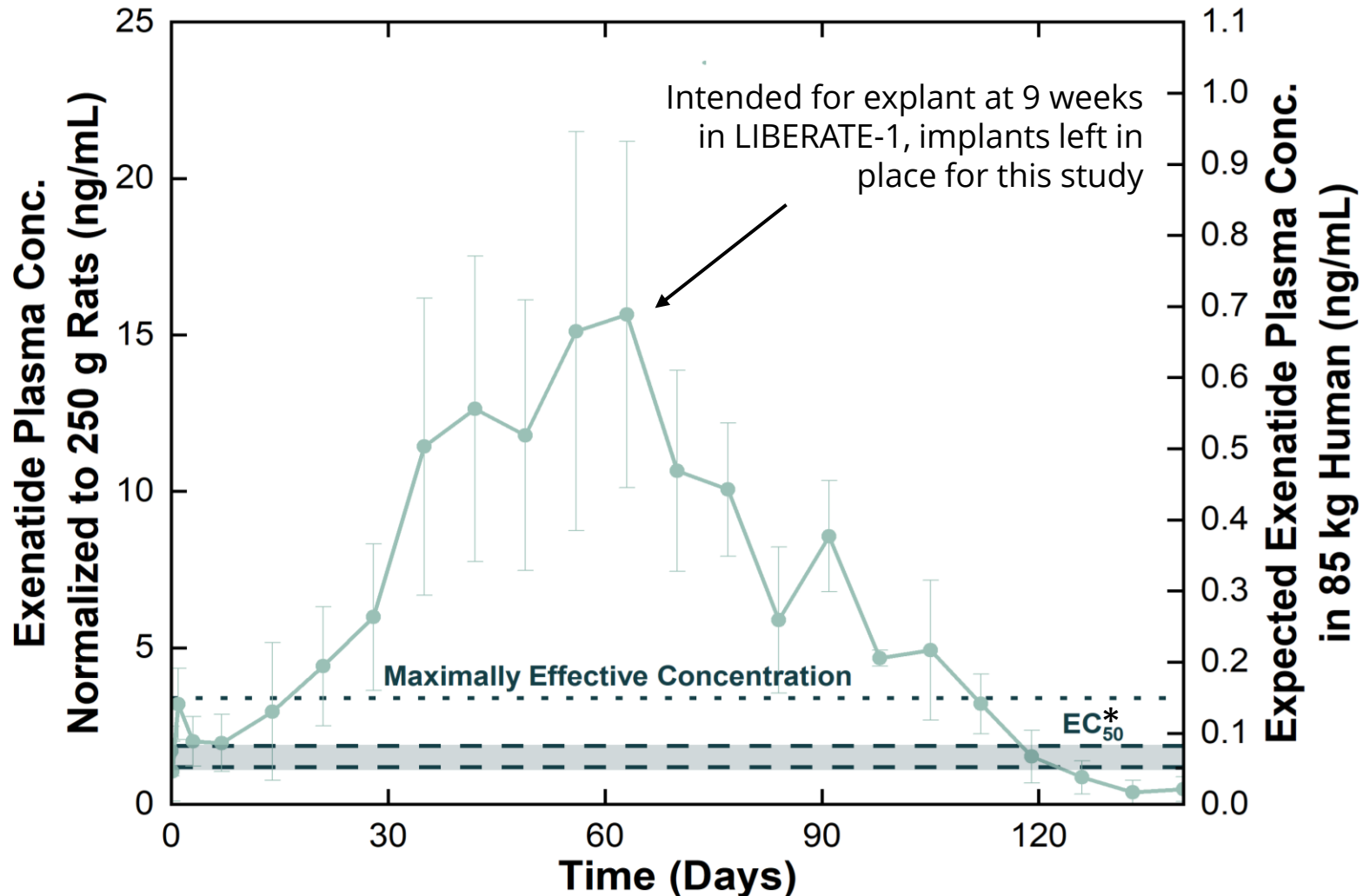
Year(s)	Milestone	Status
2024	Clinical Hold Lifted; IND cleared	June 2024

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

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

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

# 12-Week exenatide implant PK in Rats



Pharmacokinetics of 3-month exenatide implant in male Sprague-Dawley rats (n=8)

Exenatide antibody-positive animals are not included in this data set. Values are mean  $\pm$  SD.

\* The estimated exenatide EC<sub>50</sub> is 51.4 pg/mL when exenatide antibody titers are < 125 and 84 pg/mL when exenatide antibody titers are  $\geq$  125.

**Vivani Medical, Inc.**  
**Financial Information**

# Vivani Medical, Inc.

## Q2 2024: P&L Statement

### Condensed Consolidated Statements of Operations (unaudited)

<u>In Thousands, except Share Data</u>	<u>3 Months Ended</u>		<u>6 Months Ended</u>	
	<u>Jun. 30, 2024</u>	<u>Jun. 30, 2023</u>	<u>Jun. 30, 2024</u>	<u>Jun. 30, 2023</u>
<b>Operating expenses:</b>				
Research and development, net of grants	\$ 3,513	\$ 3,864	\$ 7,239	\$ 7,819
General and administrative	2,168	3,139	4,669	5,785
<b>Total operating expenses</b>	<b>5,681</b>	<b>7,003</b>	<b>11,908</b>	<b>13,604</b>
<b>Loss from operations</b>	<b>(5,681)</b>	<b>(7,003)</b>	<b>(11,908)</b>	<b>(13,604)</b>
Other income (expense), net	325	477	513	760
<b>Net income/(loss)</b>	<b>\$ (5,356)</b>	<b>\$ (6,526)</b>	<b>\$ (11,395)</b>	<b>\$ (12,844)</b>
<b>Net income/(loss) per common share – basic</b>	<b>\$ (0.10)</b>	<b>\$ (0.13)</b>	<b>\$ (0.21)</b>	<b>\$ (0.25)</b>
	-	-	-	-
<b>Wtd Avg common shares outstanding basic and diluted</b>	<b>55,021</b>	<b>50,795</b>	<b>53,612</b>	<b>50,748</b>

# Vivani Medical, Inc.

## Q2 2024: Balance Sheet

### Condensed Consolidated Balance Sheets (unaudited)

<i>In Thousands</i>	<u>Jun. 30, 2024</u>	<u>Dec. 31, 2023</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 24,919	\$ 20,654
Prepaid expenses and other current assets	1,418	2,408
<b>Total current assets</b>	<b>26,337</b>	<b>23,062</b>
Property and equipment, net	1,710	1,729
Right-of-use assets	18,801	19,616
Restricted cash	1,338	1,338
Deposits and other assets	38	52
<b>Total assets</b>	<b>\$ 48,224</b>	<b>\$ 45,797</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities	\$ 5,784	\$ 5,723
Long term operating lease liabilities	18,616	19,313
<b>Total liabilities</b>	<b>24,400</b>	<b>25,036</b>
<b>Stockholders' equity:</b>		
Total Common Stock, APIC & Other Comp Gain	133,657	119,199
Accumulated deficit	(109,833)	(98,438)
<b>Total liabilities and stockholders' equity</b>	<b>\$ 48,224</b>	<b>\$ 45,797</b>

# Vivani Medical, Inc.

## Q2 2024: Cap Table

*As of June 30, 2024*

Equity	WAEP*	Number of Shares
Common Stock		55,196,703
Stock Options	\$2.55	6,615,656
RSUs	-	695,000
Warrants	\$3.39	10,484,342
Fully Diluted Shares		70,137,371

\*Weighted Average Exercise Price

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