Nasdaq: VANI

www.vivani.com

# Vivani Medical, Inc.

***Guaranteed Adherence. Better Outcomes.***

June 2025

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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

## Anthony Baldor, MS, MBA – Chief Financial Officer

- Former CFO and Head of Business Development at Diakonos Oncology
- Former VP Corporate Strategy and Development at 4DMT
- Former Research Analyst at Jefferies
- Former Venture Capital Principal at BioInnovation Capital and Associate at RMI Partners

# Vivani Headquarters and GMP Manufacturing Facility

## I350 S. Loop Road, Alameda, California since 2023


# Vivani Medical, Inc.

1. An innovative, clinical-stage 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.

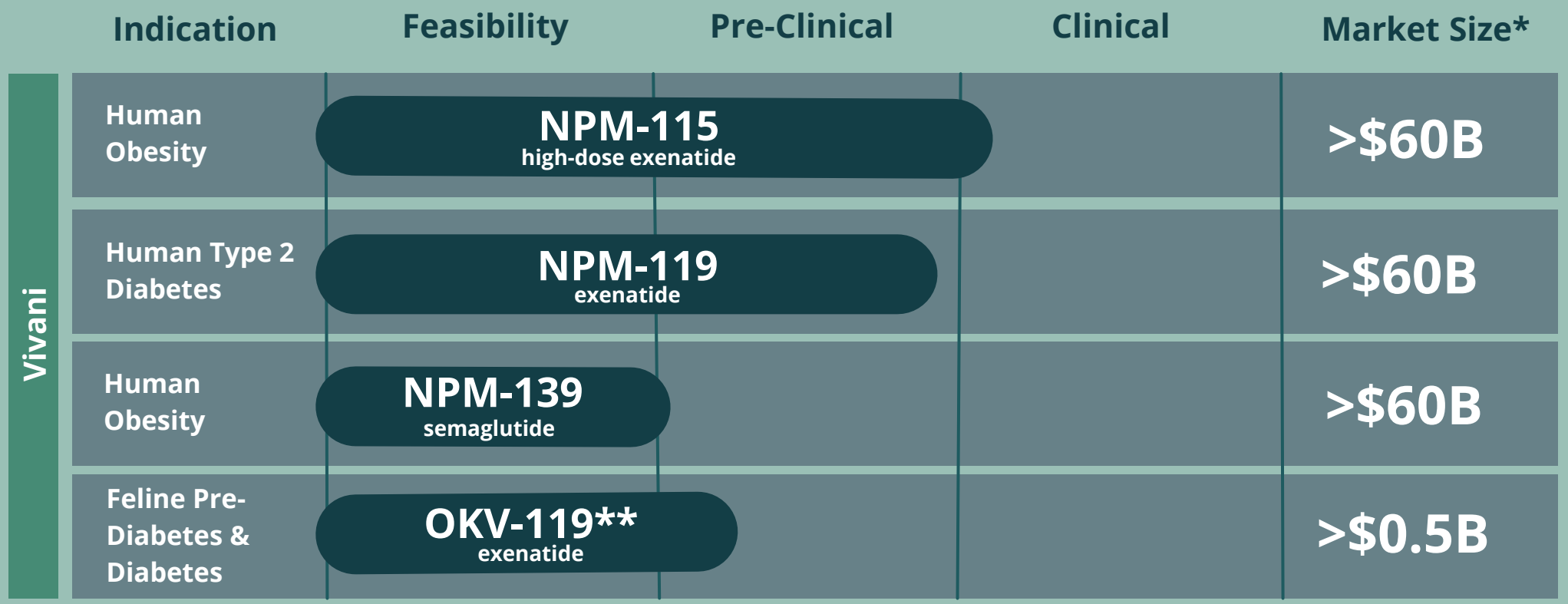
2. Lead programs include NPM-115 (high-dose exenatide) and NPM-139 (semaglutide). These miniature, subdermal, GLP-1 implants are under development for chronic weight management in obese and overweight individuals with once or twice-yearly dosing.

3. Pipeline also includes IND-cleared NPM-119 (exenatide) implant under development for type 2 diabetes designed for twice-yearly dosing.

4. Multiple potentially transformational milestones are anticipated in 2025 including completion of the First-in-human, LIBERATE-1 trial and availability of top-line data. In addition, acceleration of the NPM-139 (semaglutide implant) program toward clinical development is also anticipated.

# Company Pipeline

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



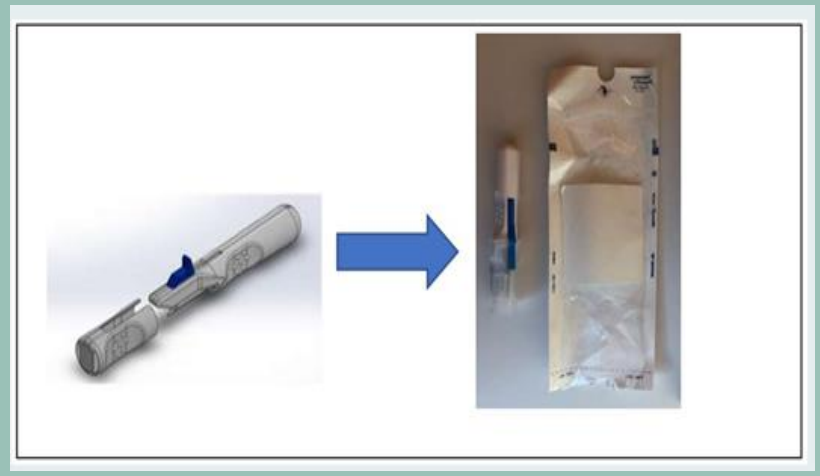

* Estimated Market Sizes where Vivani products would compete, if approved. Does not represent future sales or revenue estimates of Vivani pipeline products. Evaluate Pharma's "World Preview 2024: Pharma's Growth Burst July 2024" estimates $130B in GLP-1 sales by 2030. We assume >$60B for Obesity/Chronic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

# Drug Implants
# Proprietary Platform Technology

# GLP-1 Implant and Applicator



Approximate size of implant expected for type 2 diabetes indication



Vivani

# NanoPortal™:

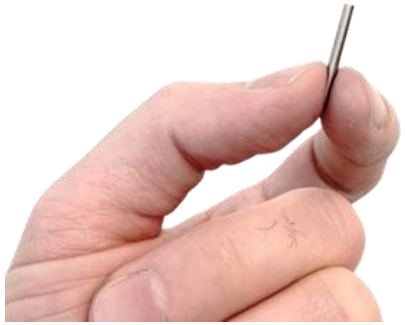
## Innovative Delivery Technology

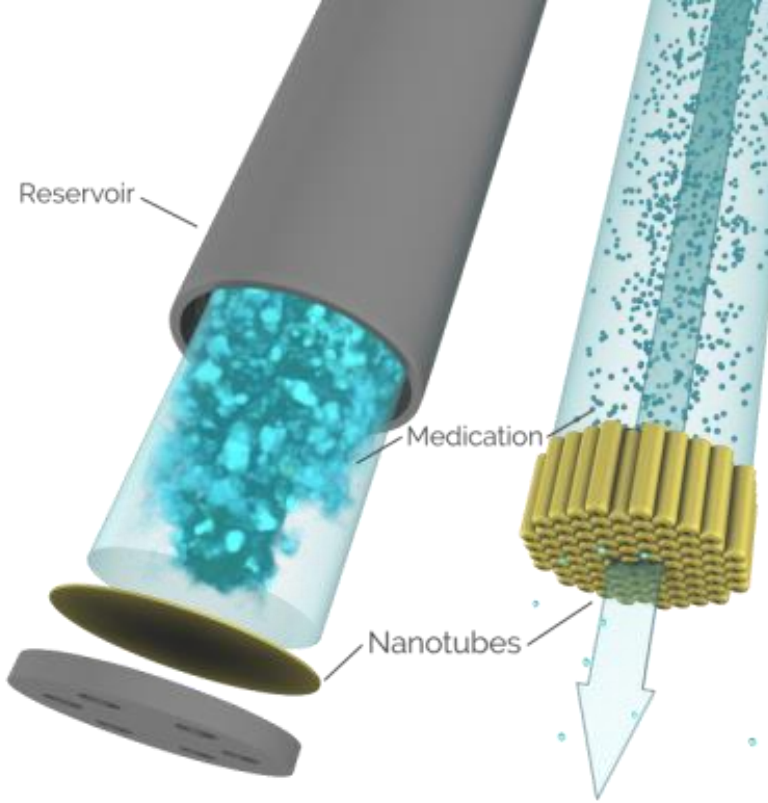
Designed to assure adherence

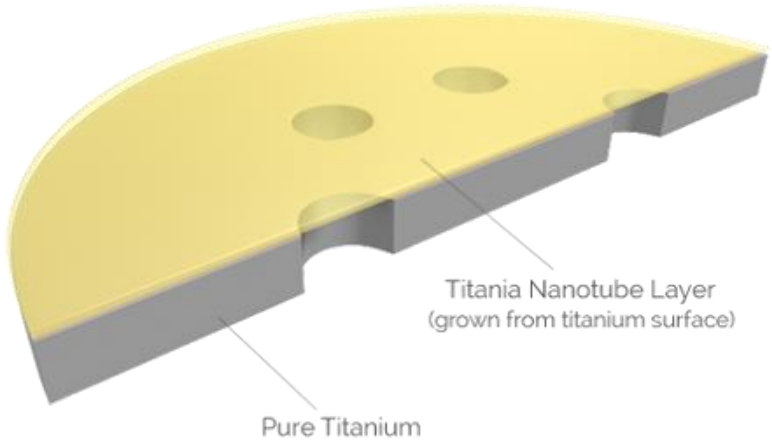
Minimally-fluctuating and tunable delivery profiles

Potential application with many molecular types

**Drug Reservoir**





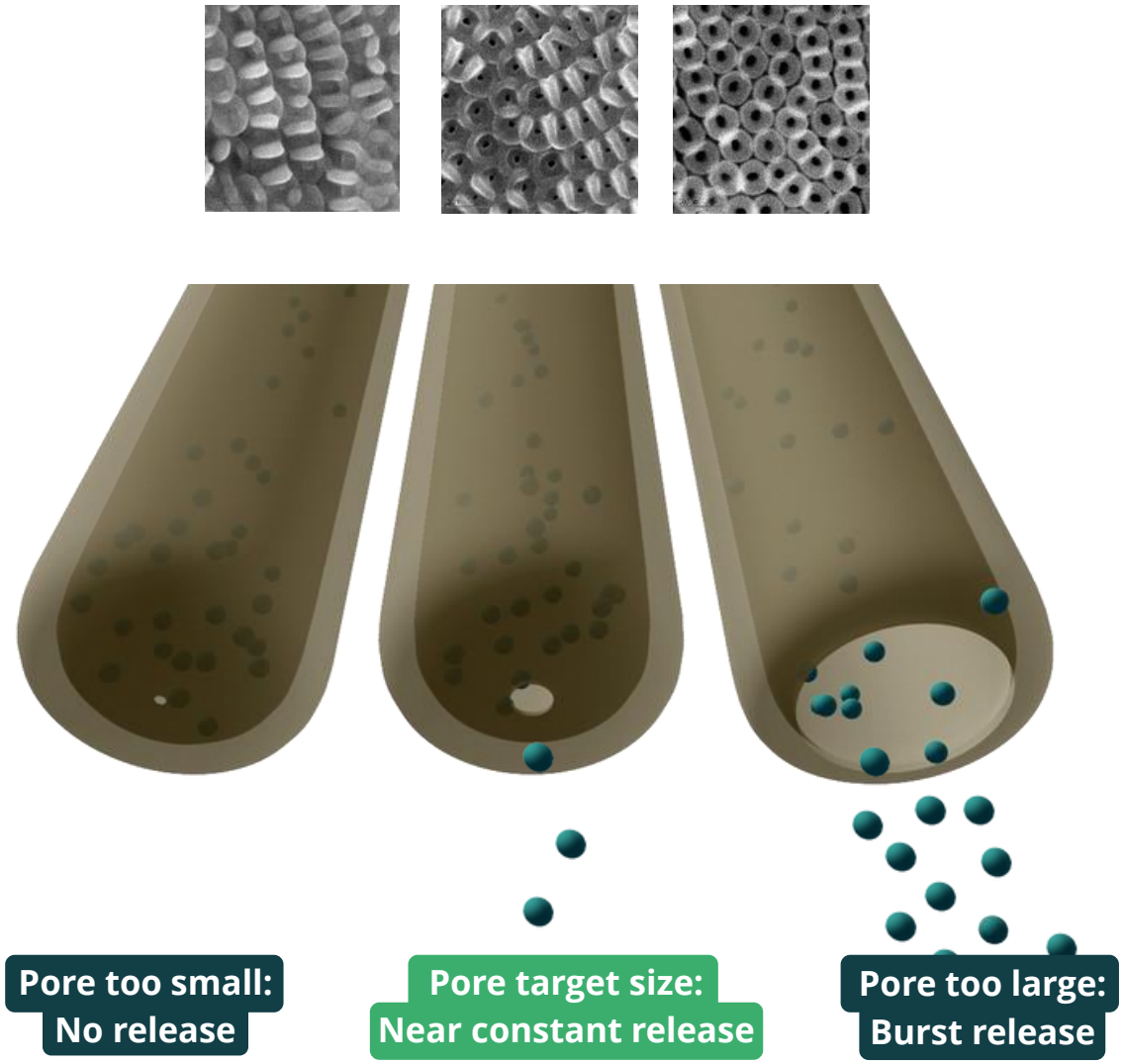




**Nanotube Membrane**

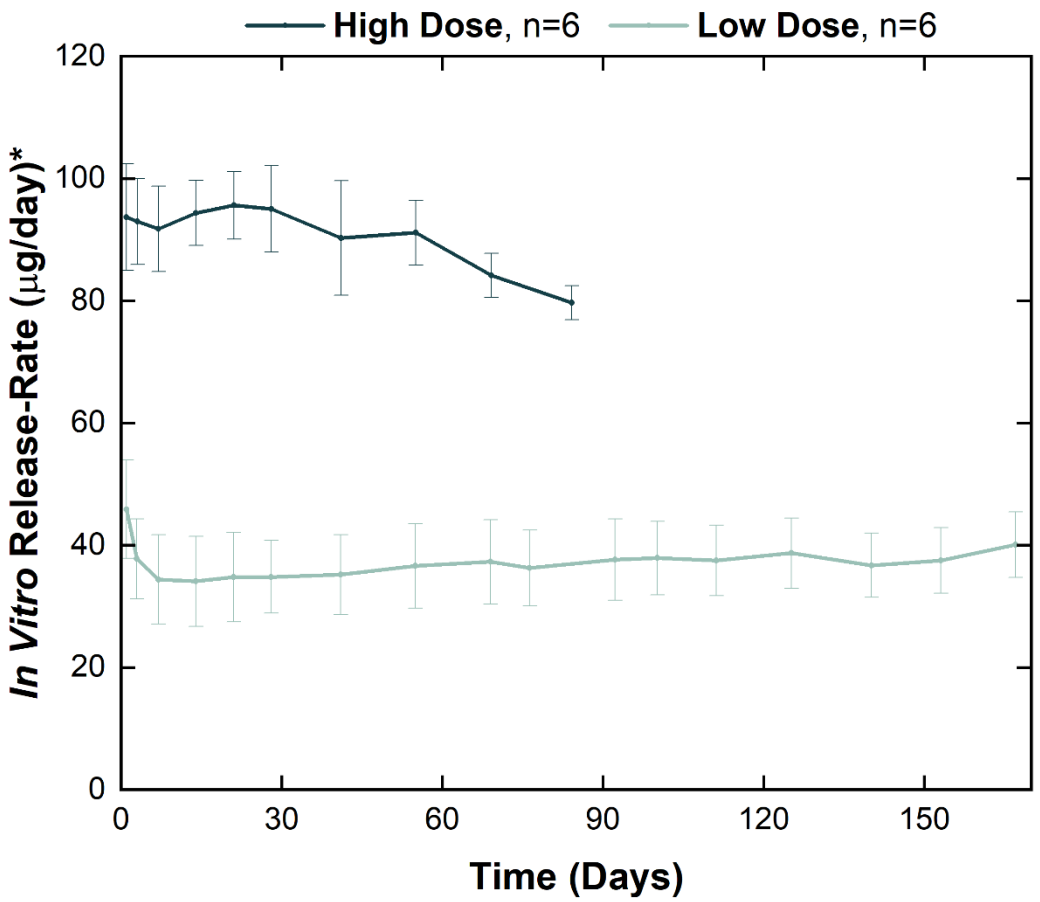
# NanoPortal™

## How it Works...

By precisely adjusting the nanotube pore size to slightly greater than the size of specific drug molecules, the interactions between the drug and nanotube walls can result in desirable release profiles over time, including **near constant release**



# NanoPortal delivers near-constant / minimally-fluctuating drug release

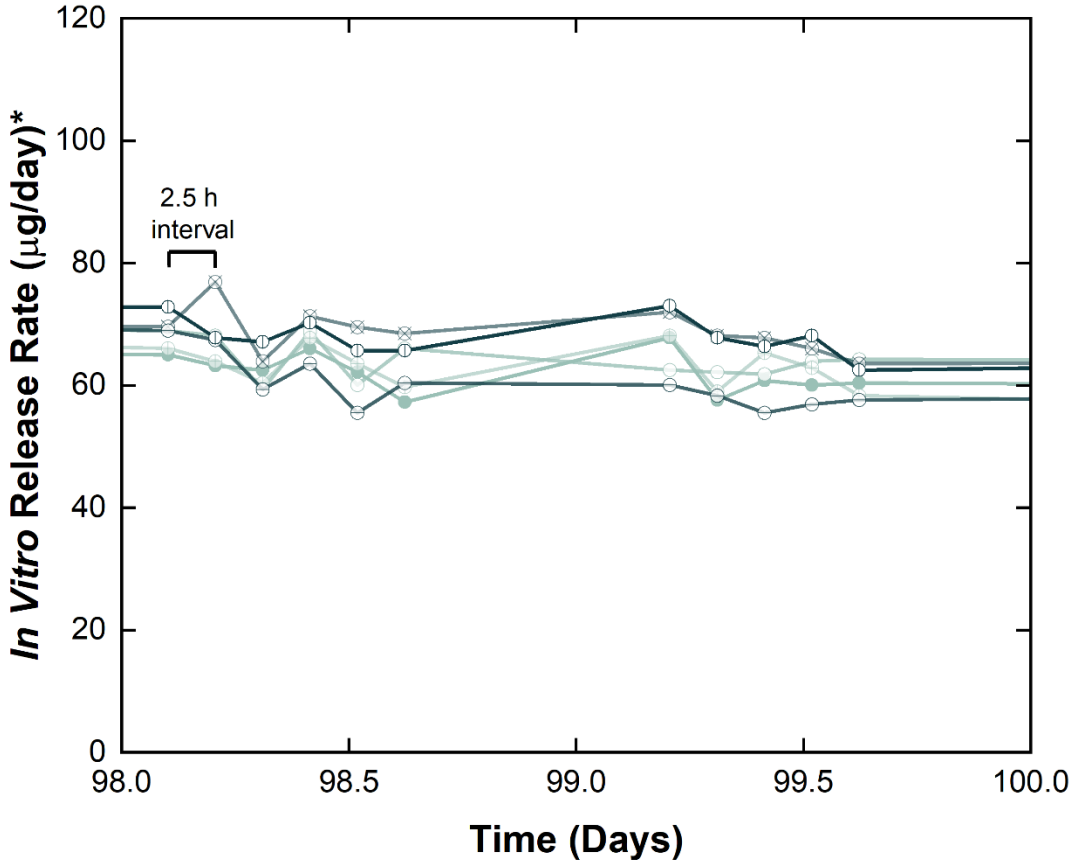



Day 1 timepoint includes cumulative release over the first day including a separately measured 1st hour of release, which was ~7 µg for the high-dose and ~4 µg for the low-dose. Values are mean ± SD.

*Release-rates include exenatide and related substances.

## Minimal Fluctuations with 2.5-hour interval sampling

### Individual Release Profiles (n=6)




Fluctuations during each 2.5-hour interval are within measurement error

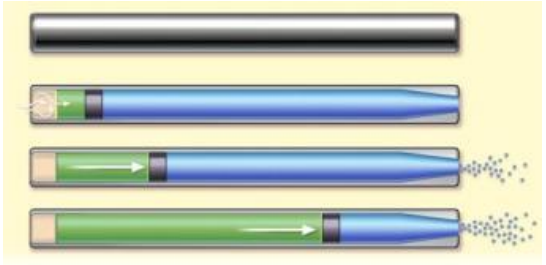
# NanoPortal™ is a Platform Technology

## Broad Potential Application Can Support Portfolio of New Drug Implants

- Minimized Implant Size
- Extendable Implant Duration
- Tunable Delivery Rate
- Tunable Delivery Profile

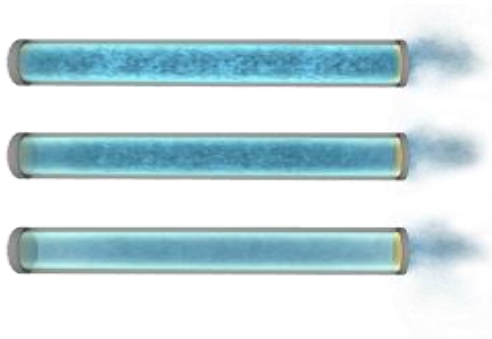
# NanoPortal implant technology designed to avoid challenges faced by other implants

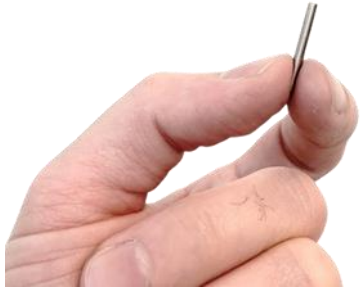
## Six-month exenatide implant Osmotic Pump (Intarcia)



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

## Six-month exenatide implant NanoPortal™ (Vivani)



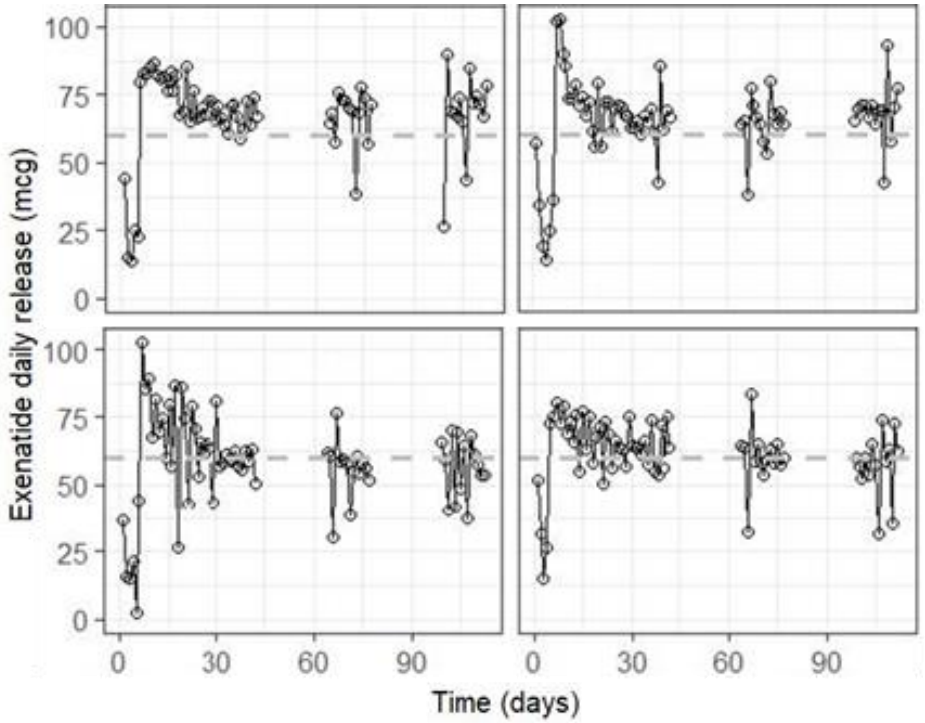


- **Minimally fluctuating drug release** profile observed in pre-clinical studies directly addresses ITCA 650 regulatory challenges
- **Smaller Device** (2.2mm x 21.5mm)*
- Insertion using **smaller 11-gauge needle**

*Approximate expected size of Type 2 Diabetes implant

# NanoPortal addresses key ITCA-650 release-rate variability issue flagged by FDA as root cause of non-approvability

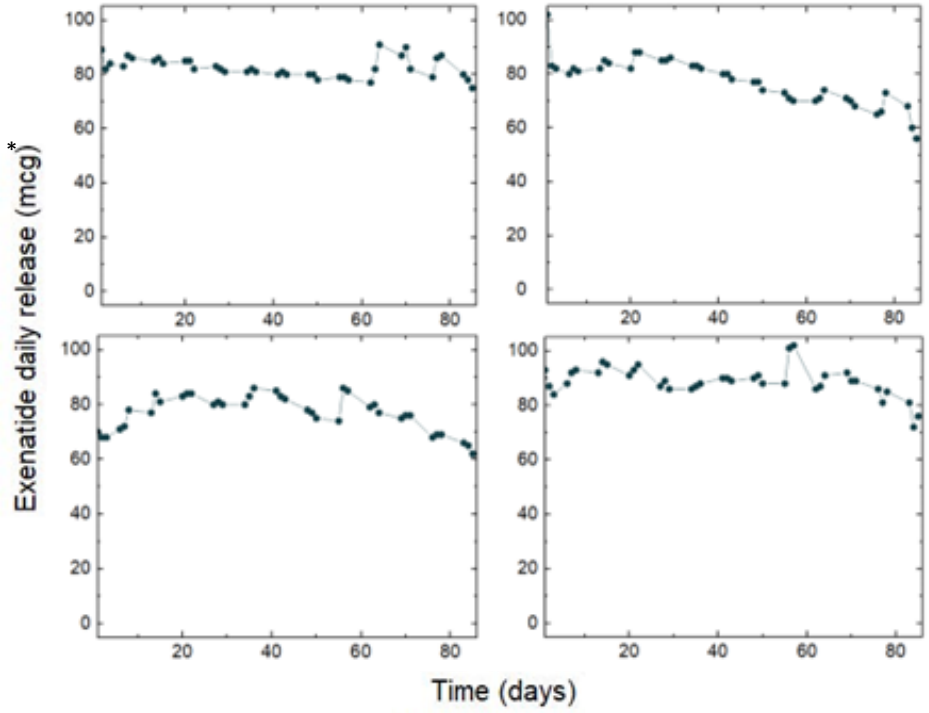
## Osmotic Pump, ITCA 650 (Intarcia)




*In vitro* data, including daily release intervals, from the 4 ITCA 650 devices with the highest day-to-day variability out of 12 tested, presented by FDA during September 2023 Advisory Committee Hearing with Intarcia

*"The clinical data in the three pivotal clinical trials for ITCA 650 including the high rates of GI side effects, discontinuations, and an increased risk of AKI comprise safety signals whose root cause can reasonably be concluded to be irregular and uncontrolled exenatide release."* FDA Memorandum July 29, 2022, page 33

## NanoPortal™ (Vivani)




*In vitro* data, including daily release intervals, from the 4 NanoPortal exenatide implants with the highest day-to-day variability out of 17 tested, provided by Vivani to FDA and helped facilitate IND clearance

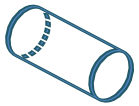
*Data includes exenatide and related substances

# Better adherence is expected to improve GLP-1 effectiveness and tolerability

**Medication non-adherence and tolerability are significant unmet needs for GLP-1 treatments**

**Adherence/Persistence to GLP-1s is suboptimal**, at only ~30-40% adherent patients during year one and ~36-47% persistence by end of year one (Ozempic/Wegovy)[1]. Discontinuation leads to **immediate hunger-rebound induced weight regain**.

**GI side effects** occur in a **majority of patients**[2] when GLP-1 plasma levels rise at each dose escalation. **Missed doses** inadvertently **cause additional dose escalations**, likely **exacerbating GI side effects**.



**Vivani's NanoPortal™ implant is designed to prevent missed doses and minimize plasma level fluctuations to improve real-world GLP-1 treatment outcomes[3,4]**

1. Gleason et al., 2024 2 Aldhaleei et al., 2024 3 Polonsky et al., 2016; 4.Hamersky et al 2019

# Vivani Lead Program
# NPM-115

## High-Dose Exenatide Implant for Chronic Weight Management

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

# Priority Program NPM-115:

**Development of 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]
- Preclinical data with NPM-115 has demonstrated similar magnitude of weight loss for exenatide and semaglutide injection
- NPM-115 target profile may provide an attractive alternative to life-long injections or pills for long-term maintenance of GLP-1 therapy for weight management

[1, 2] Novo Nordisk 2023 Annual Report

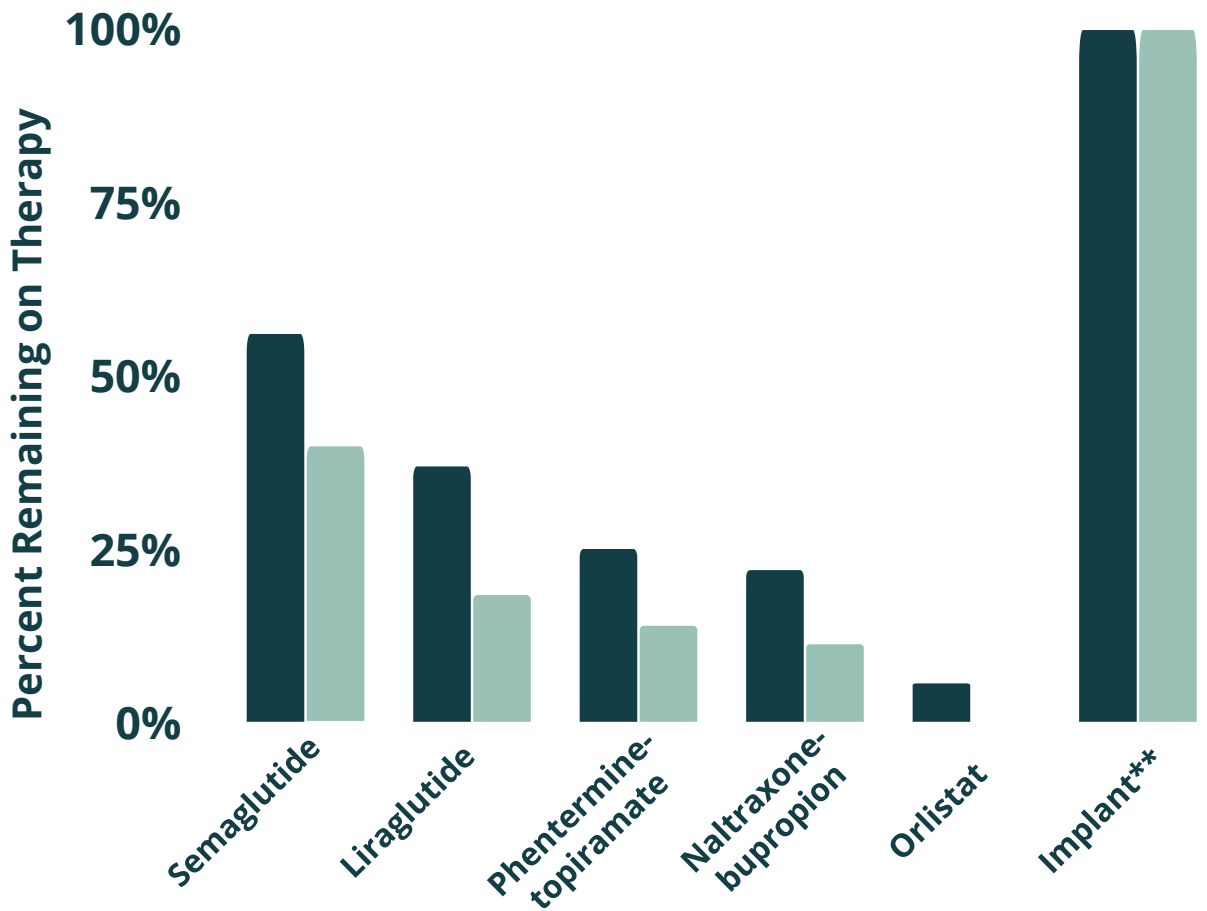
# Weight Loss Medicines Associated With Adherence Challenges

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

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

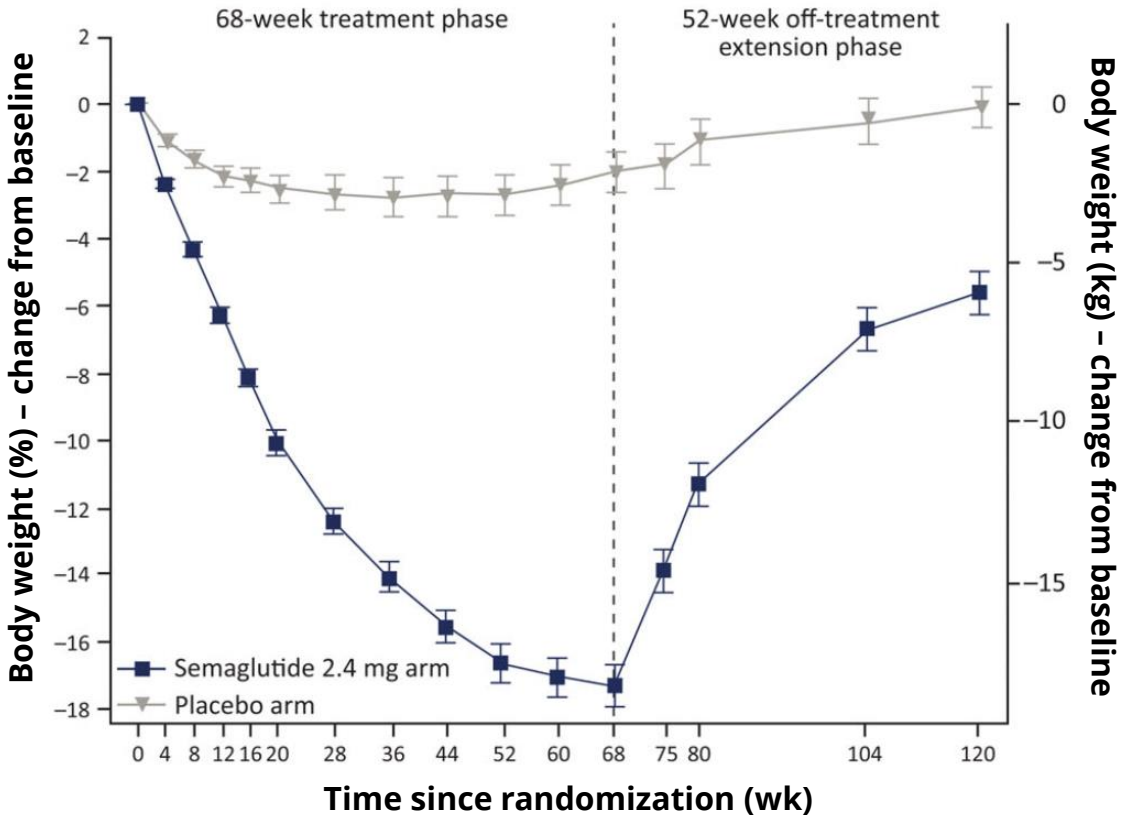
* Published in Obesity, December 8, 2023

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

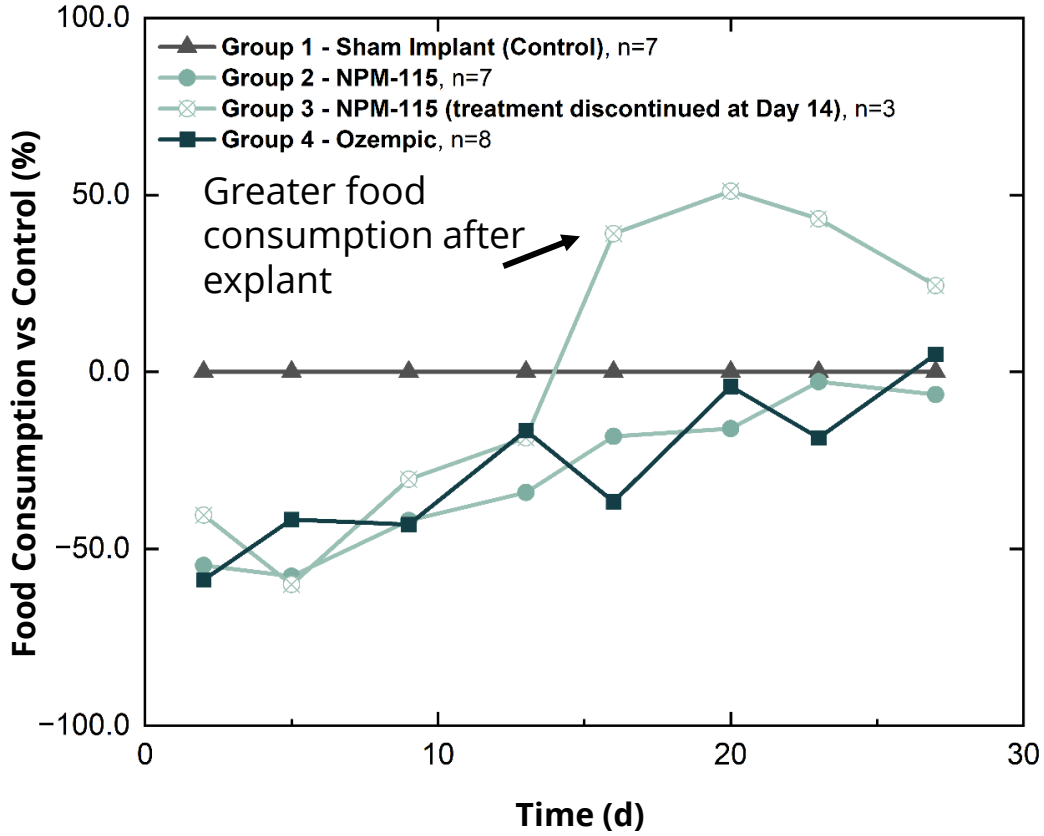



** Implant not included in this Large Retrospective Cohort Study, included for illustrative purposes only

# GLP-1 Discontinuation Can Lead to Rapid Hunger-Induced Weight Rebound in Animals and Humans



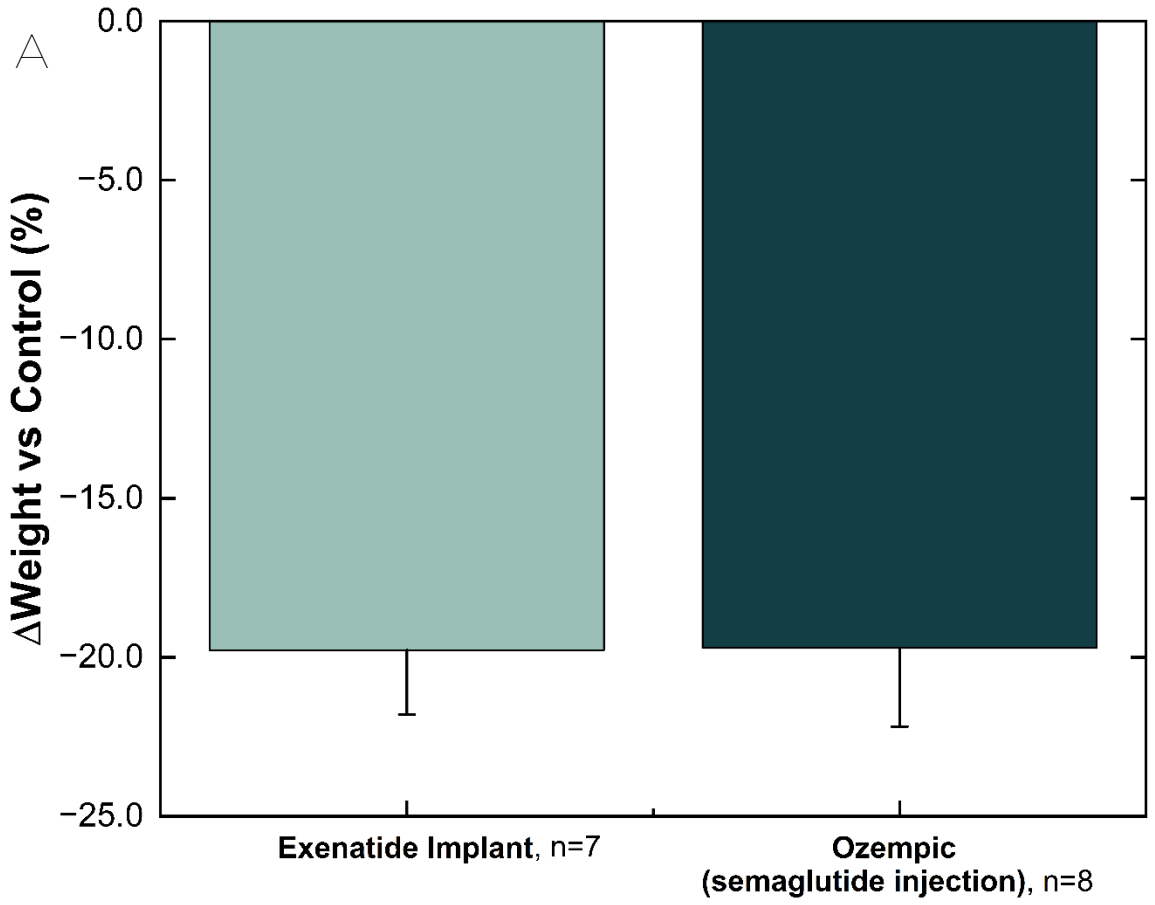

STEP 1 Extension: Semaglutide Withdrawal

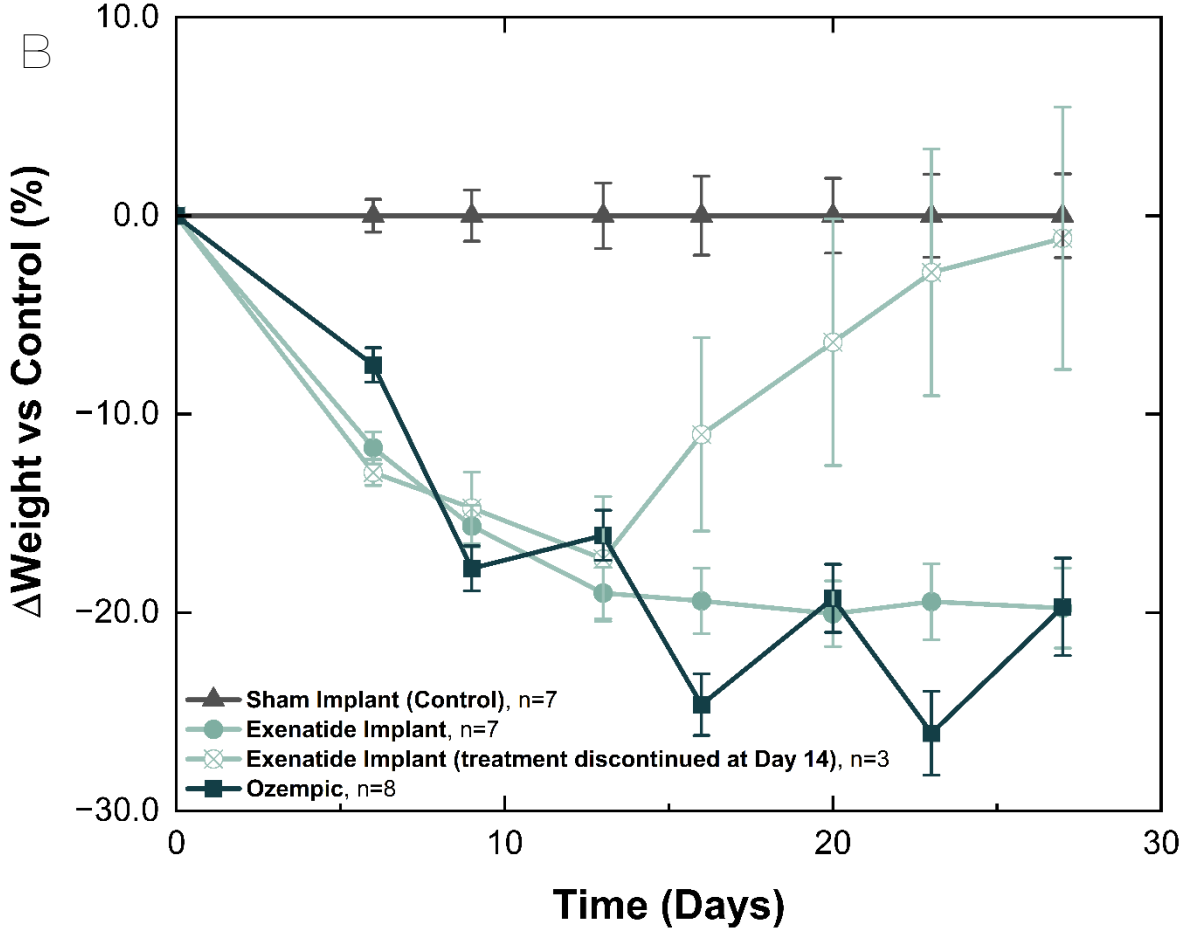



Vivani Data in Diet-Induced Obese Mice

**Sudden GLP-1 withdrawal produces immediate rebound hunger, leading to rapid weight regain mediated by greater food consumption**

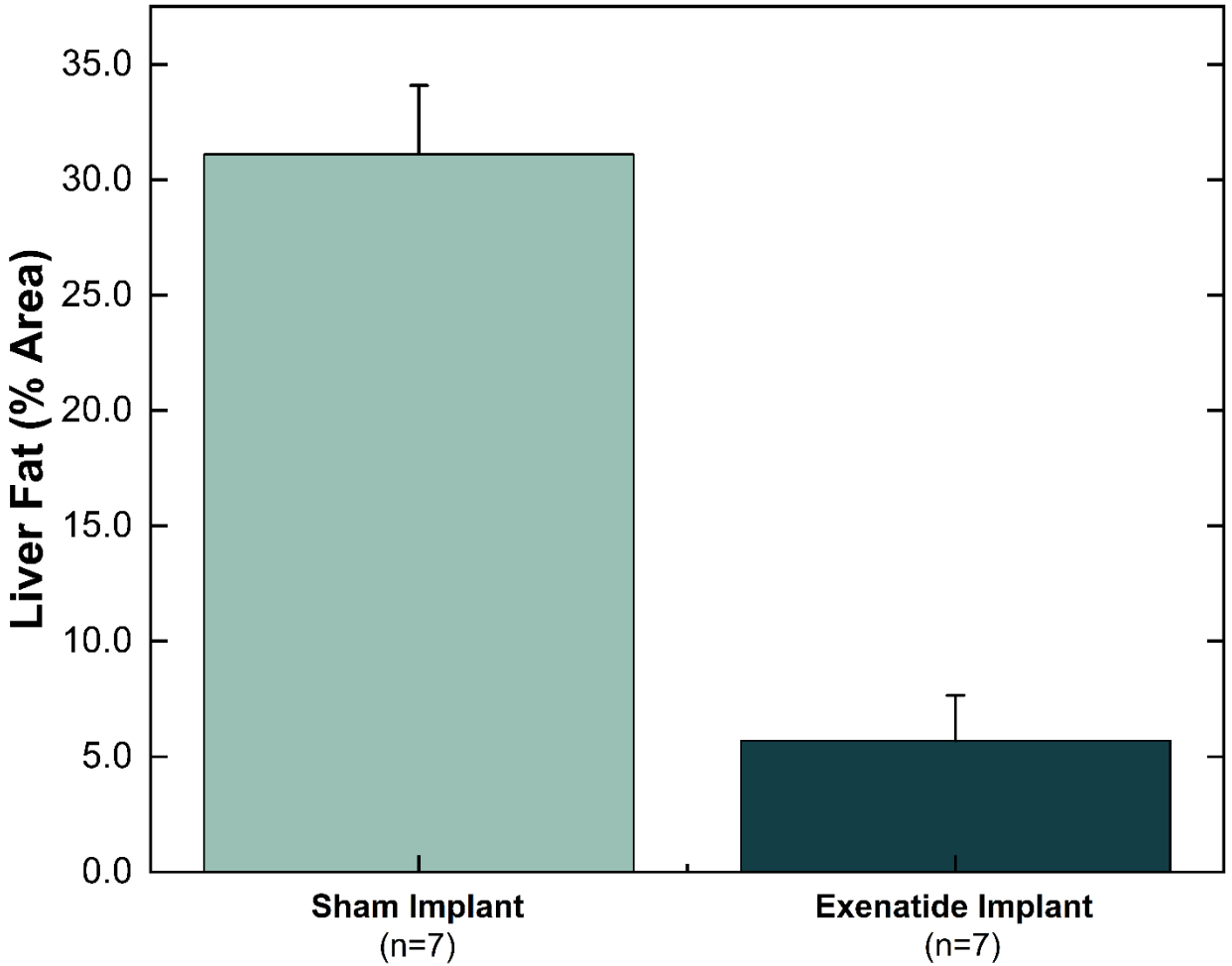
# Exenatide implant associated with comparable weight loss to semaglutide in preclinical study



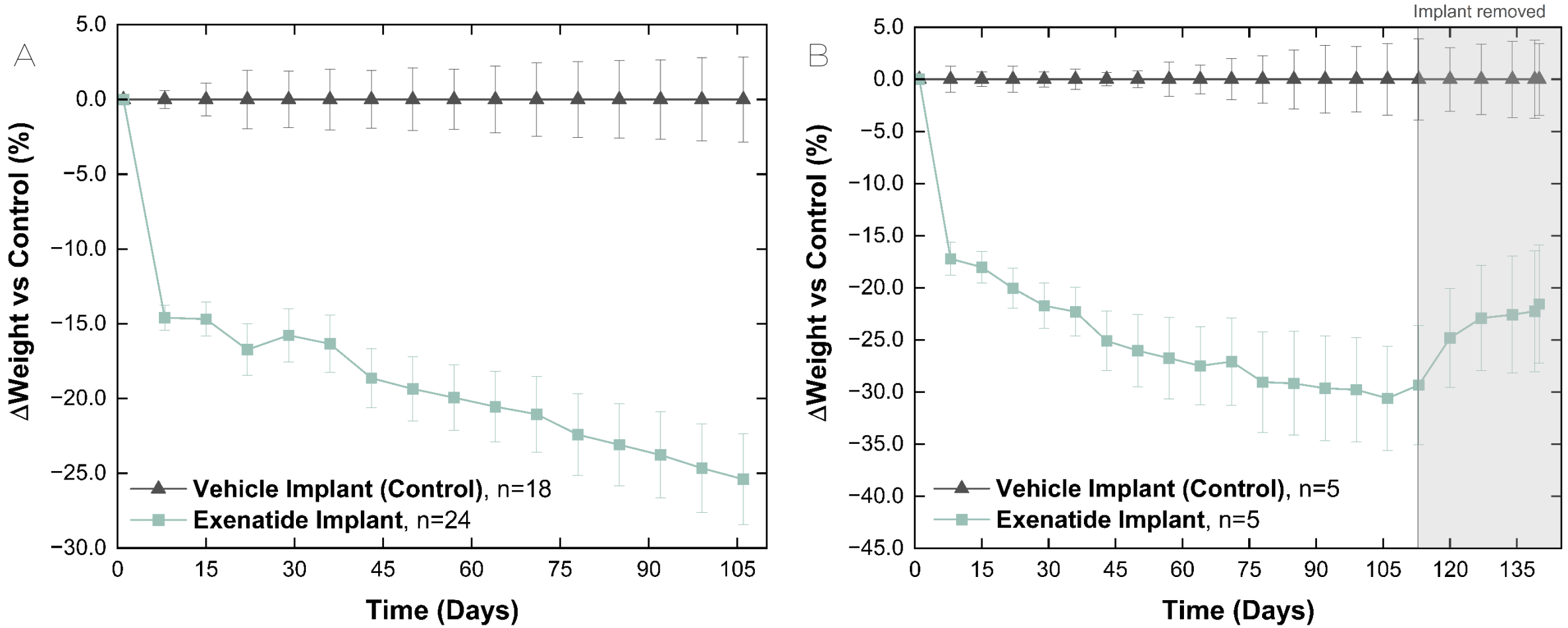

**Weight loss in high fat diet-induced obese mice. (A)** % weight change from baseline for a single administration of exenatide implant (~530 nmol/kg/day) vs weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant) at 28 days; **(B)** % weight change from baseline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

# Exenatide implant reduces liver fat by 82% in obese mice after 12 weeks



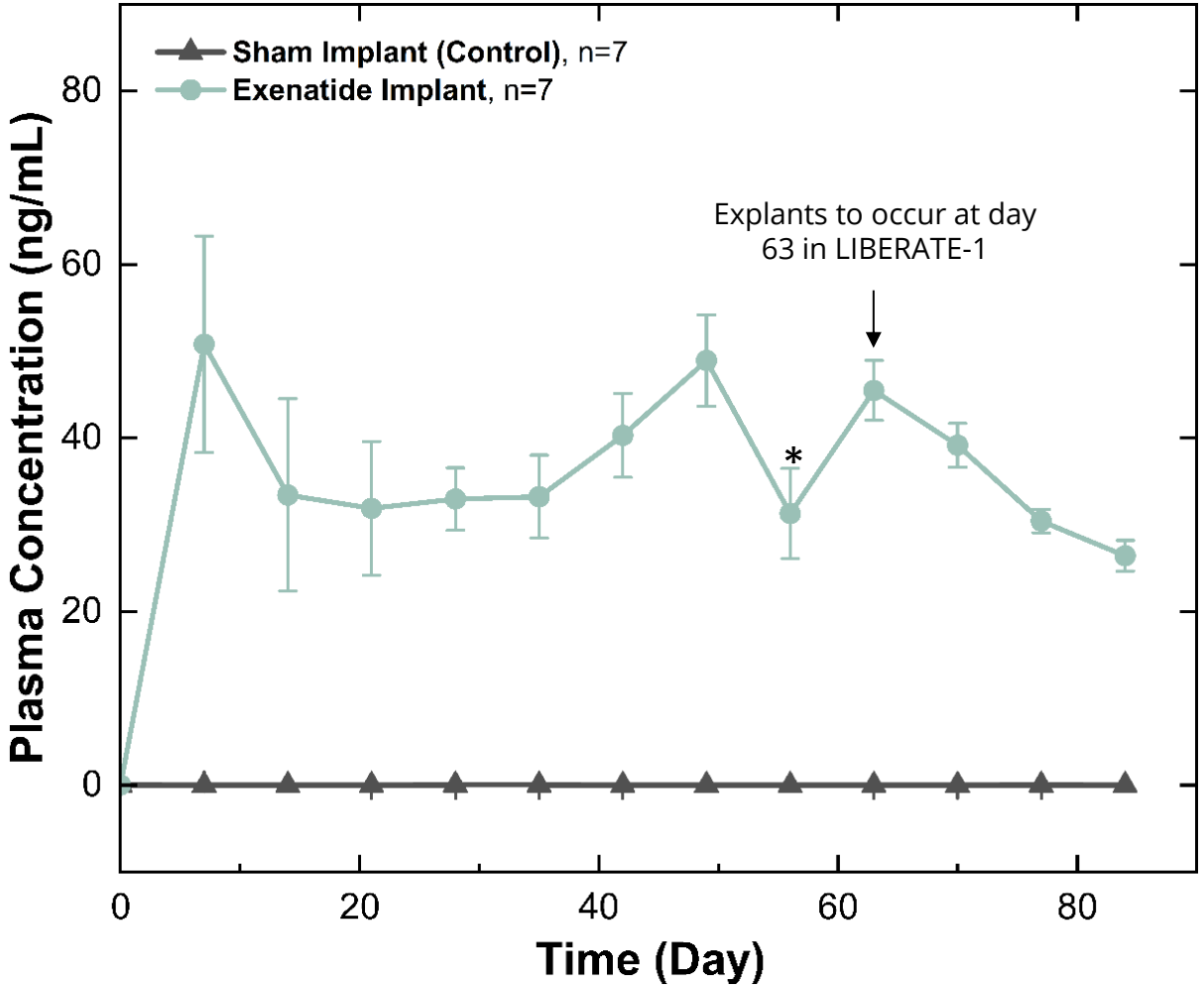

**Liver fat reduction in high fat diet-induced obese mice.** Liver fat % area for exenatide implant vs sham implant 12 weeks after a single administration. Liver fat % area is calculated using Oil Red O (ORO) staining. Values are mean ± SE. These results are numerically consistent with a similar investigation in which liver fat content was evaluated in high fat diet-induced obese mice that received semaglutide injections.

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



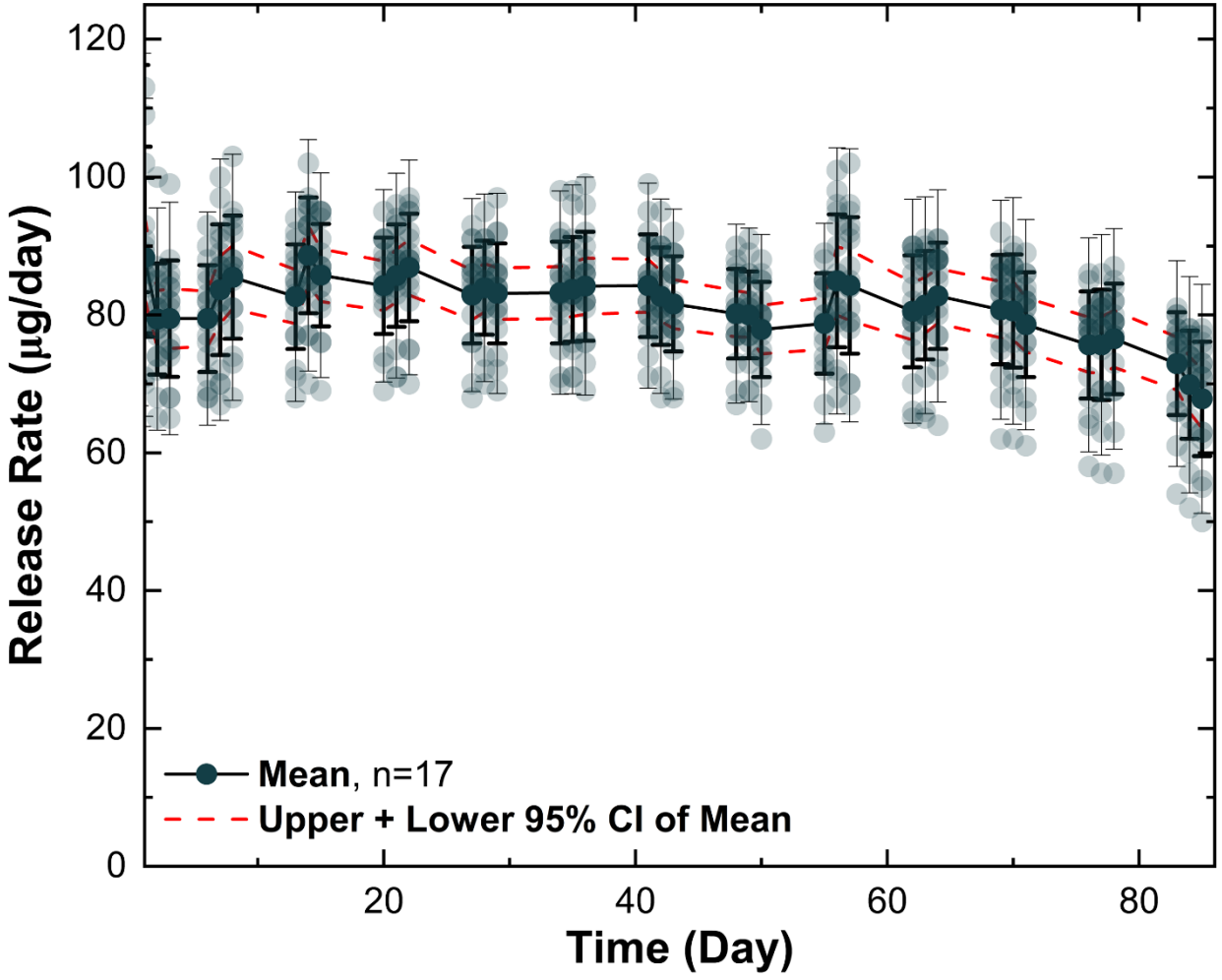

**Weight difference from control in healthy Sprague-Dawley Rats.** % weight change from baseline for a single administration of exenatide implant in a study associated with NPM-119 (~320 nmol/kg/day) corrected to control (vehicle implant). **(A)** All animals measured through 105 days of treatment; **(B)**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

# *In vivo* and *in vitro* performance of 12-week exenatide implant configuration to be studied in LIBERATE-1



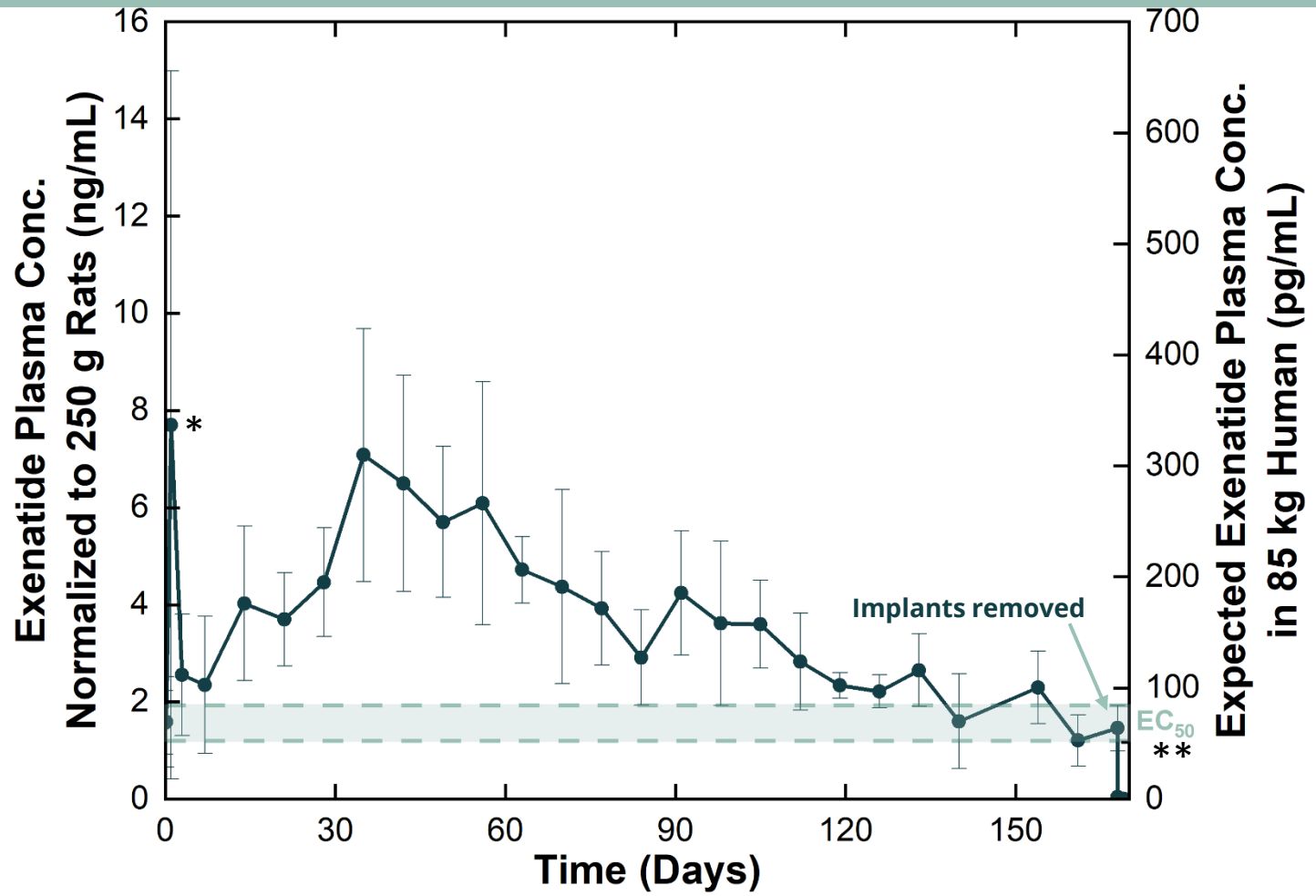

***In vivo* pharmacokinetics of 12-week exenatide implant and sham implant in high fat diet-induced obese mice (n=7 per group).** Values are mean ± SE.

*Day 56 values reported as measured, but sample handling error suspected to have occurred.




***In vitro* release-rate of exenatide implant to be used in LIBERATE-1 (n=17).** Individual values are included for each timepoint. Each week consists of two 24-hour intervals and a 5-day interval. Values are mean ± 1 SD (bold) and ± 2 SD. Release-rates include exenatide and related substances.

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

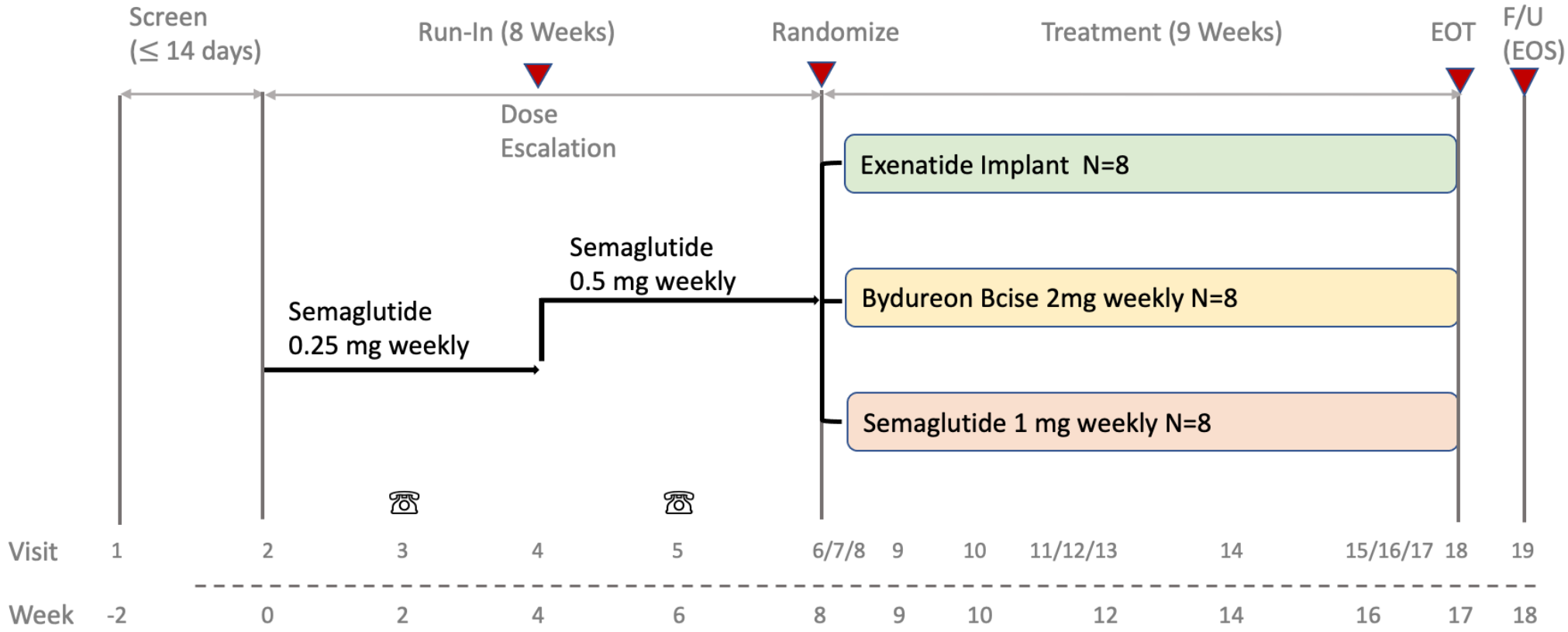



**Pharmacokinetics of 6-month exenatide implant in male Sprague-Dawley rats (n=6)**
Exenatide antibody-positive animals are not included in this data set. Values are mean ± SD.
*2 of 6 implants are responsible for higher Day 1 exenatide concentrations which is not expected to occur in the configuration to be used in the clinic.
** The estimated exenatide EC50 is 51.4 pg/mL when exenatide antibody titers are < 125 and 84 pg/mL when exenatide antibody titers are >= 125. These exenatide EC50 estimates are consistent with the exenatide EC50 estimate, 83.5 pg/mL, from the FDA Clinical Pharmacology review of BYDUREON

# First-in-Human Trial: LIBERATE-1, Now Fully Enrolled

**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 NPM-115 Program to Evaluate High Dose Exenatide Implant for Chronic Weight Management | November 2023 |
| 2024 | Reported Positive Weight Loss in Preclinical Study | February 2024 |
| 2024 | Announced Initiation of Screening and Enrollment of First-In-Human, LIBERATE-1 Study in Obese and Overweight Patients | December 2024 |
| 2025 | First Subject entered Study Run-In phase | January 2025 |
| **2025** | **First Subject implanted, Full Enrollment** | **March 2025** |
| 2025 | Results of LIBERATE-1 available | Expected Mid-2025 |

November 2023 – Vivani announced NPM-115 clinical program (high-dose exenatide implant) for chronic weight management.

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

December 2024 – Company announced screening and enrollment of LIBERATE-1 in obese and overweight patients in Australia.

March 2025 – NPM-115 GLP-1 implants successfully inserted into all 8 subjects. Full study enrollment completed.

# NPM-119

## Exenatide Implant for Type 2 Diabetes

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

# NPM-119

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

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

[1] 2023 Novo Nordisk Annual Report
[2] Guo 2016
[2,3] Carls et al., 2017
[4] IMS 2013 Report

# Current Drug Adherence Challenge

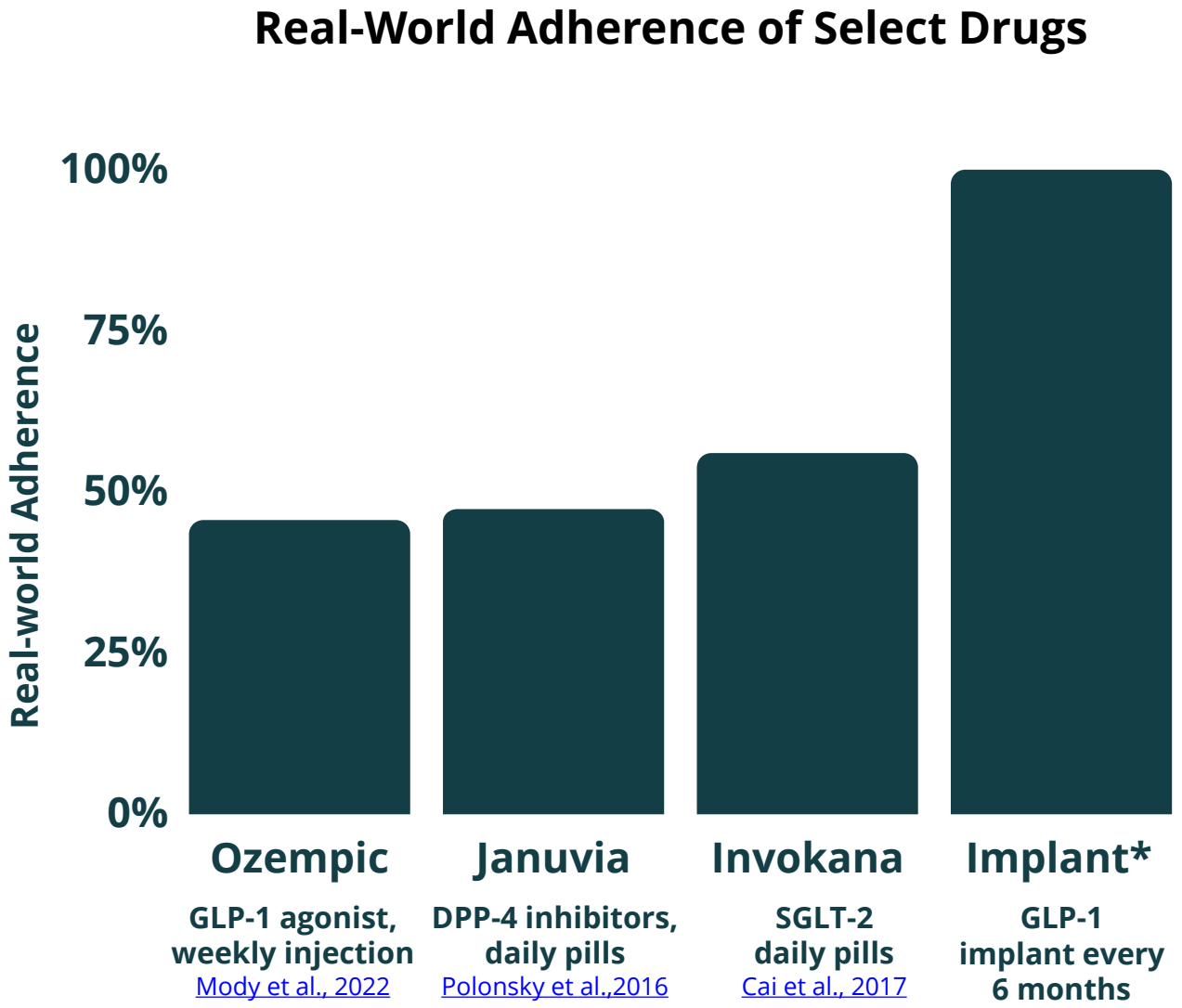
***"Drugs don't work in people that don't take them"***

## 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**

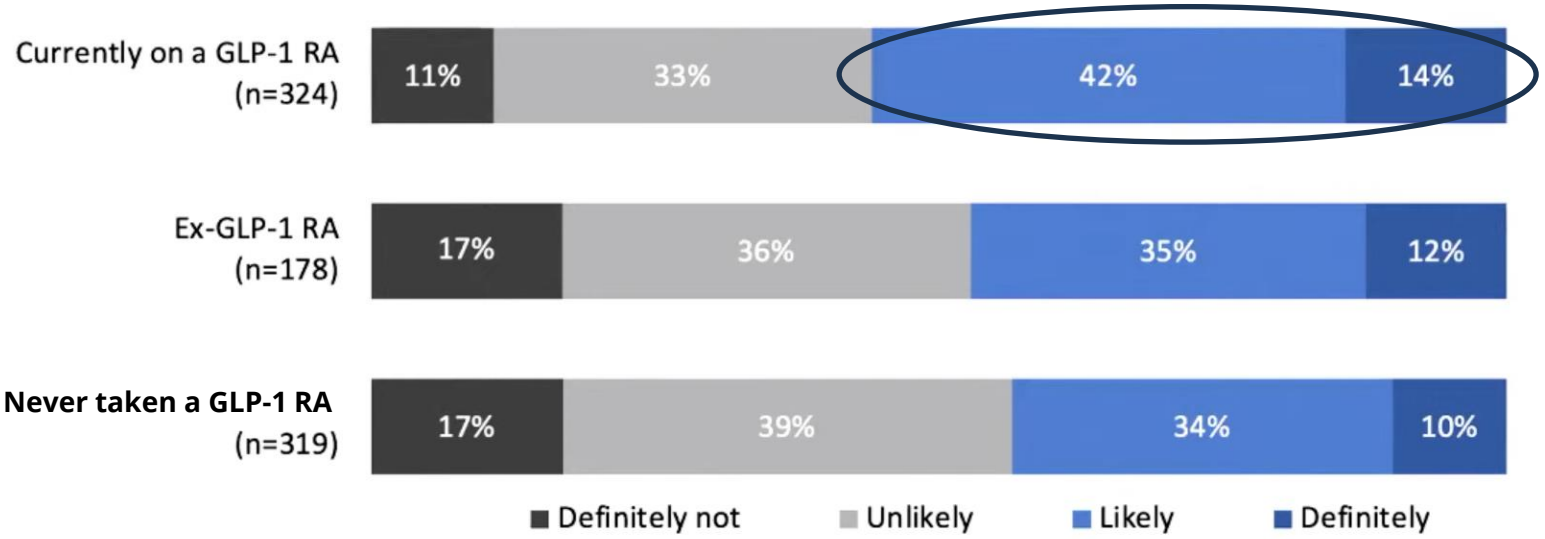



* NPM-119's exenatide implant – under development, designed to enable 100% adherence, not approved in any market

# 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?"

dQ&A

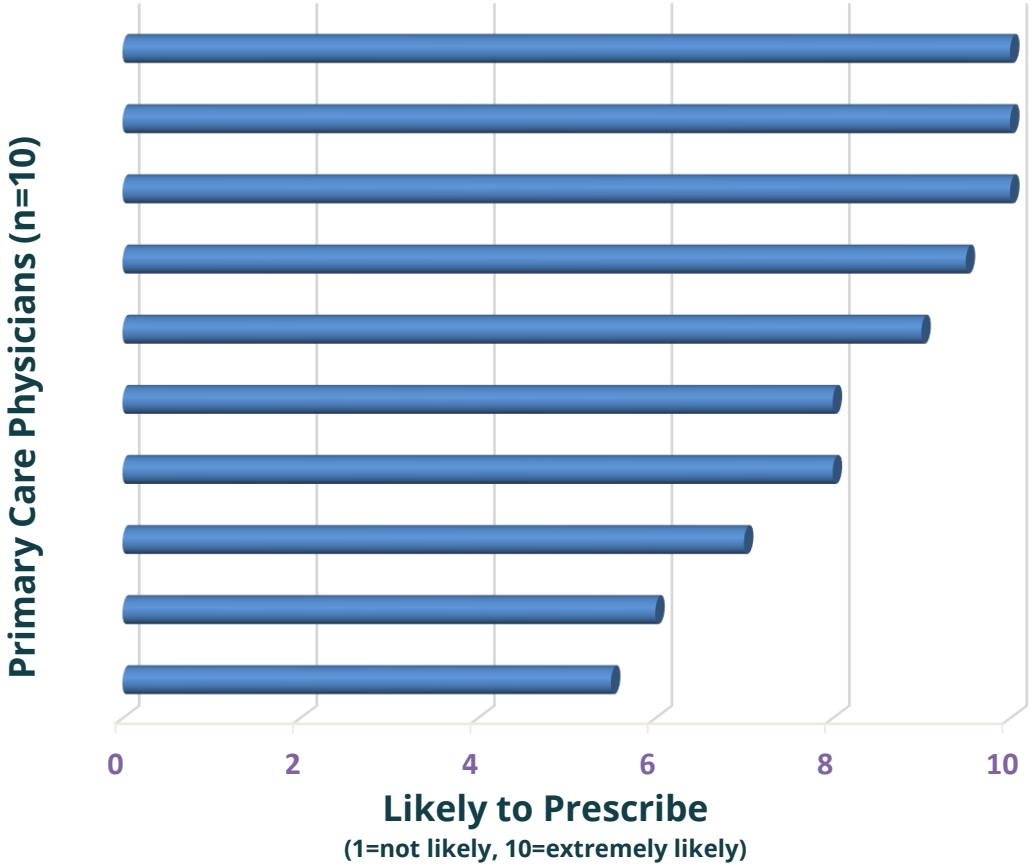


dQ&A insights reported market research during FDA Advisory Board to review ITCA 650 (exenatide implant) on September 21, 2023

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

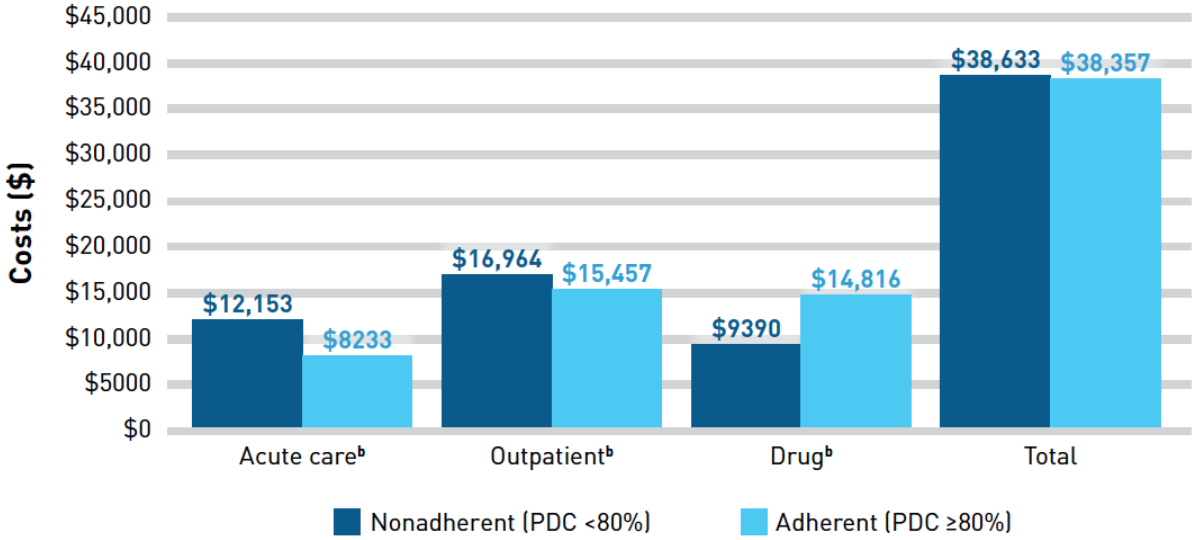
## Prescribing Rating, Average 8.3 out of 10

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




## Adherence = Lower Acute Care & Outpatient Costs

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




Curtis et al., 2017

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

# Vivani Lead Program
# NPM-139

## Semaglutide Implant for Chronic Weight Management

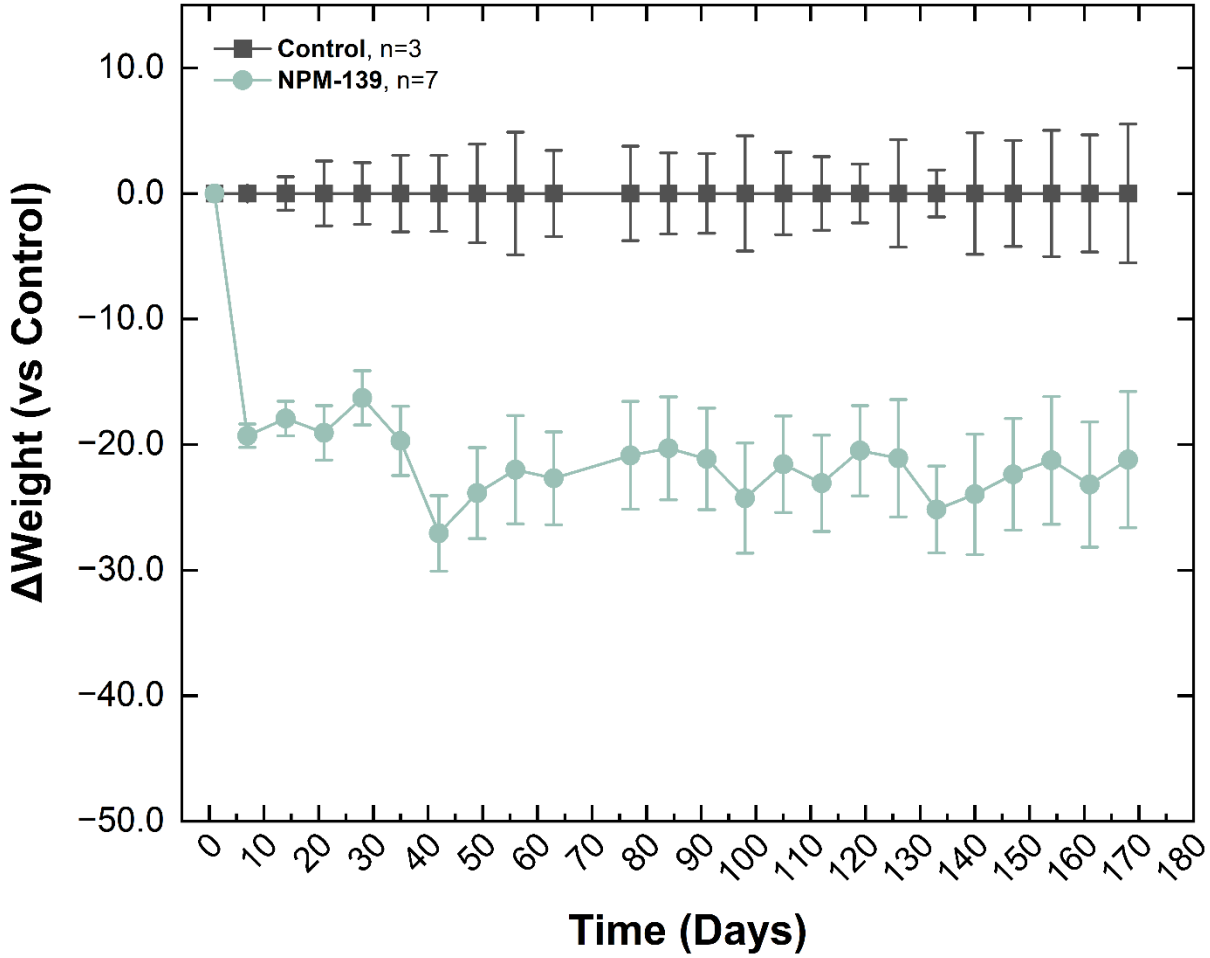
**Targeting the Rapidly Growing GLP-1 RA Market**

# Priority Program NPM-139:

**Development of once or twice-yearly Semaglutide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Chronic Weight Management in Obese or Overweight Patients**

- Semaglutide products Ozempic® and Wegovy® generated **~$25B in sales in 2024**
- More than half of patients regularly miss doses based on real-world adherence data
- NPM-139 is initially being designed for once or twice-yearly dosing.
- In addition to obesity, the semaglutide implant is also under consideration for treatment of type 2 diabetes

# NPM-139 - NanoPortal™ Successfully Delivers Active Semaglutide for 6 Months




**Body weight measurements of semaglutide implant (n=7). Weight difference versus control group in healthy Sprague-Dawley Rats. % weight change from baseline for NPM-139 (semaglutide implant) corrected to control (sham implant). Values are mean ± SE.**
Study was initially designed for a 3-month duration but was extended due to positive results. The implant from one rat contained no semaglutide at 6 months and the data from that rat is excluded from this analysis.

# Vivani Medical, Inc.
# Financial Information

# Vivani Medical, Inc.
# Q1 2025: Income/(Loss) Statement

**Condensed Consolidated Statement of Operations**

| In Thousands, except Share Data | 3 Months Ended Mar. 31, 2025 | Mar. 31, 2024 |
|---|---|---|
| **Operating expenses:** | | |
| Research and development, net of grants | 4,217 | 3,726 |
| General and administrative | 2,340 | 2,501 |
| Total operating expenses | 6,557 | 6,227 |
| **Loss from operations** | **(6,557)** | **(6,227)** |
| Other income (expense), net | 255 | 188 |
| **Net income/(loss)** | **$ (6,302)** | **$ (6,039)** |
| **Net income/(loss) per common share – basic** | **$ (0.11)** | **$ (0.12)** |
| **Wtd Avg common shares outstanding basic & diluted** | **59,236** | **52,202** |

# Vivani Medical, Inc.
# Q1 2025: Balance Sheet

**Condensed Consolidated Balance Sheet**

| In Thousands | Mar. 31, 2025 (unaudited) | Dec. 31, 2024 (audited) |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 13,008 | $ 18,352 |
| Prepaid expenses and other current assets | 1,842 | 2,090 |
| Total current assets | 14,850 | 20,442 |
| Property and equipment, net | 1,609 | 1,693 |
| Right-of-use assets | 17,523 | 17,957 |
| Restricted cash | 1,338 | 1,338 |
| Deposits and other assets | 132 | 131 |
| **Total assets** | **$ 35,452** | **$ 41,561** |
| **LIABILITIE S AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Current liabilities | $ 6,199 | $ 5,986 |
| Long term operating lease liabilities | 17,629 | 17,965 |
| **Total liabilities** | **23,828** | **23,951** |
| **Stockholders' equity:** | - | - |
| Total Common Stock, APIC & Other Comp Gain | 139,850 | 139,534 |
| Accumulated deficit | (128,226) | (121,924) |
| Total stockholders' equity | 11,624 | 17,610 |
| **Total liabilities and stockholders' equity** | **$ 35,452** | **$ 41,561** |

An additional ~$11.25M in proceeds is expected to be received by March 2026 from completed equity financing agreements

# Vivani Medical, Inc.
# Q1 2025: Cap Table

| *As of March 31, 2025* | | |
|---|---|---|
| **Equity** | **WAEP*** | **Number of Shares** |
| Common Stock | | 59,243,903 |
| Stock Options | $2.47 | 7,051,195 |
| RSUs | - | 695,000 |
| Warrants | $3.45 | 8,569,894 |
| Fully Diluted Shares | | 75,559, 992 |

*Weighted Average Exercise Price

# Vivani Medical, Inc.

1. An innovative, clinical-stage 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 programs include NPM-115 (high-dose exenatide) and NPM-139 (semaglutide). These miniature, subdermal, GLP-1 implants are under development for chronic weight management in obese and overweight individuals with once or twice-yearly dosing.

3. Pipeline also includes IND-cleared NPM-119 (exenatide) implant under development for type 2 diabetes designed for twice-yearly dosing.

4. Multiple potentially transformational milestones are anticipated in 2025 including completion of the First-in-human, LIBERATE-1 trial and availability of top-line data. In addition, acceleration of the NPM-139 (semaglutide implant) program toward clinical development is also anticipated.