



Nasdaq: VANI

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 utilizes a miniature, six-month, GLP-1 (high-dose exenatide) implant under development for chronic weight management in obese or overweight patients.
- 3 Pipeline includes IND-cleared NPM-119 utilizes a 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	NPM-115 high-dose exenatide			>\$60B
	Human Type 2 Diabetes	NPM-119 exenatide			>\$60B
	Human Obesity	NPM-139 semaglutide			>\$60B
	Feline Pre-Diabetes & Diabetes	OKV-119** 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.

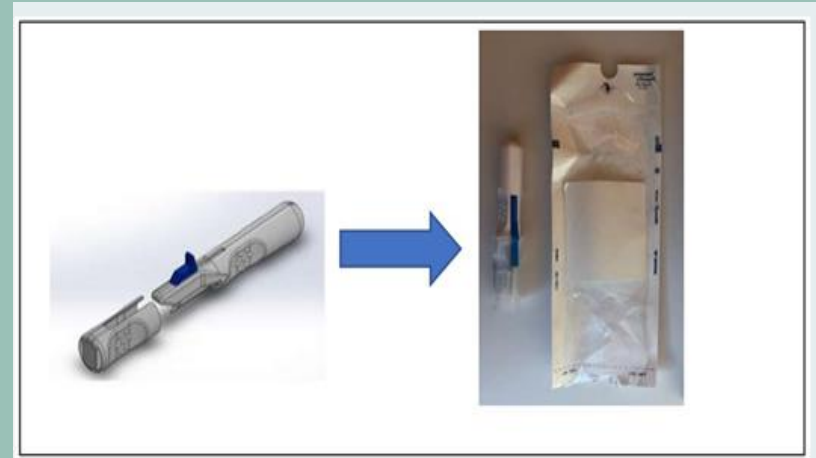
** In Partnership with Okava Pharmaceuticals, Inc.

Drug Implants
Proprietary Platform Technology

GLP-1 (exenatide) Implant and Applicator



Implant size depicted represents approximate size of dose expected for T2DM indication



NanoPortal™:

Innovative Delivery Technology



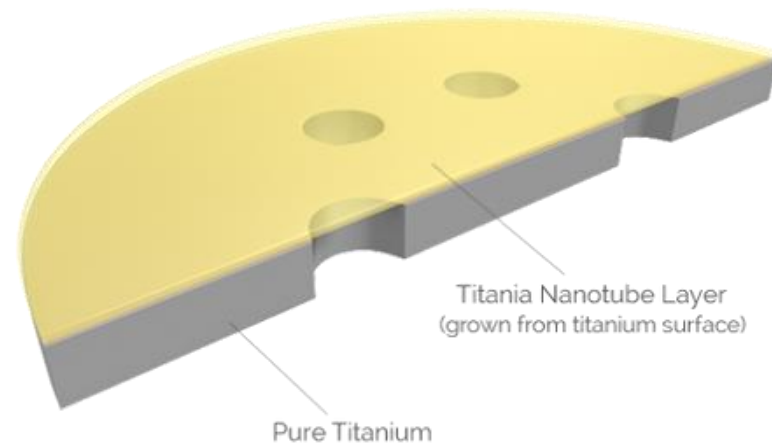
Designed to assure adherence



Minimally-fluctuating and tunable delivery profiles



Potential application with many molecular types

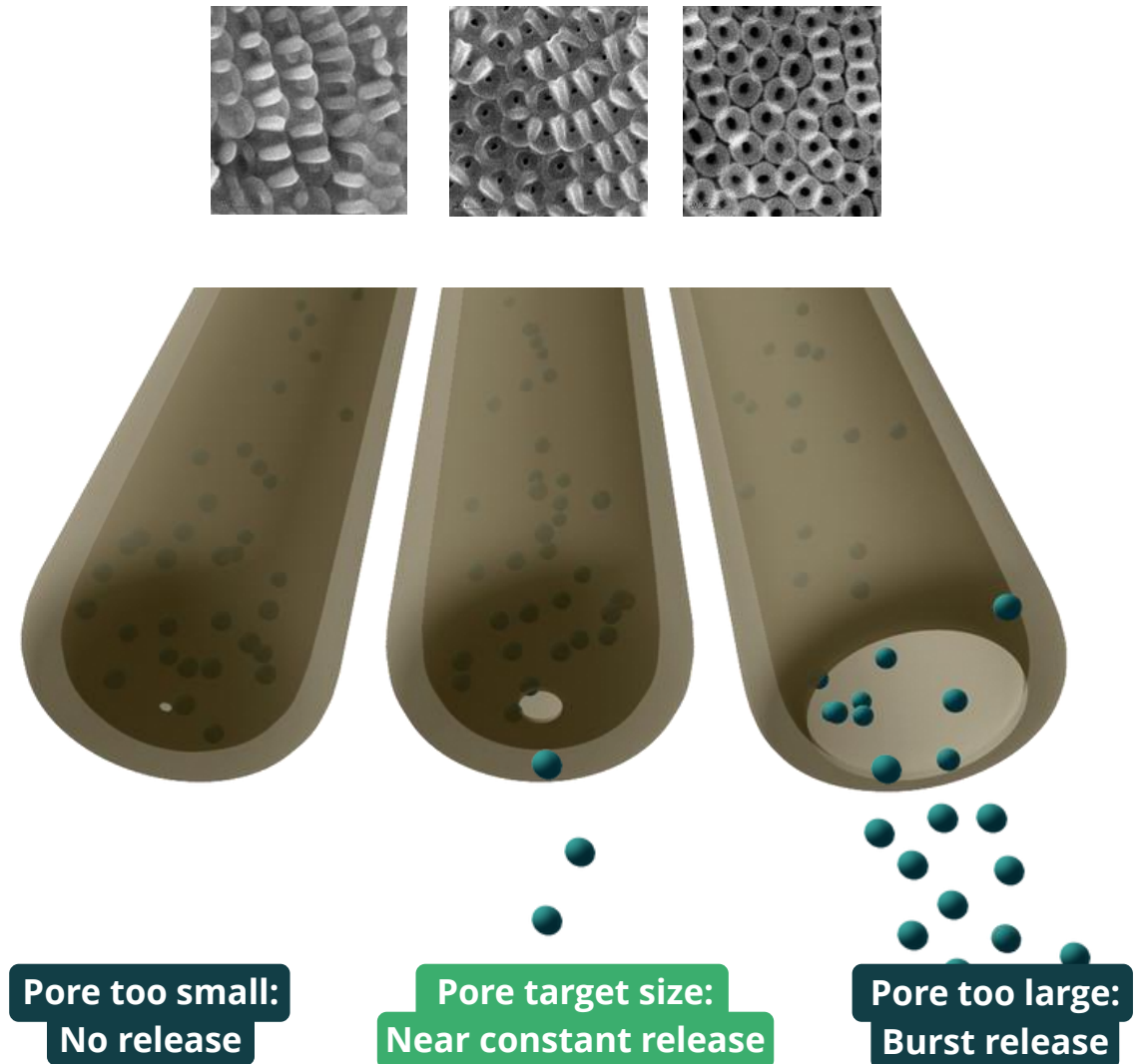


Nanotube Membrane

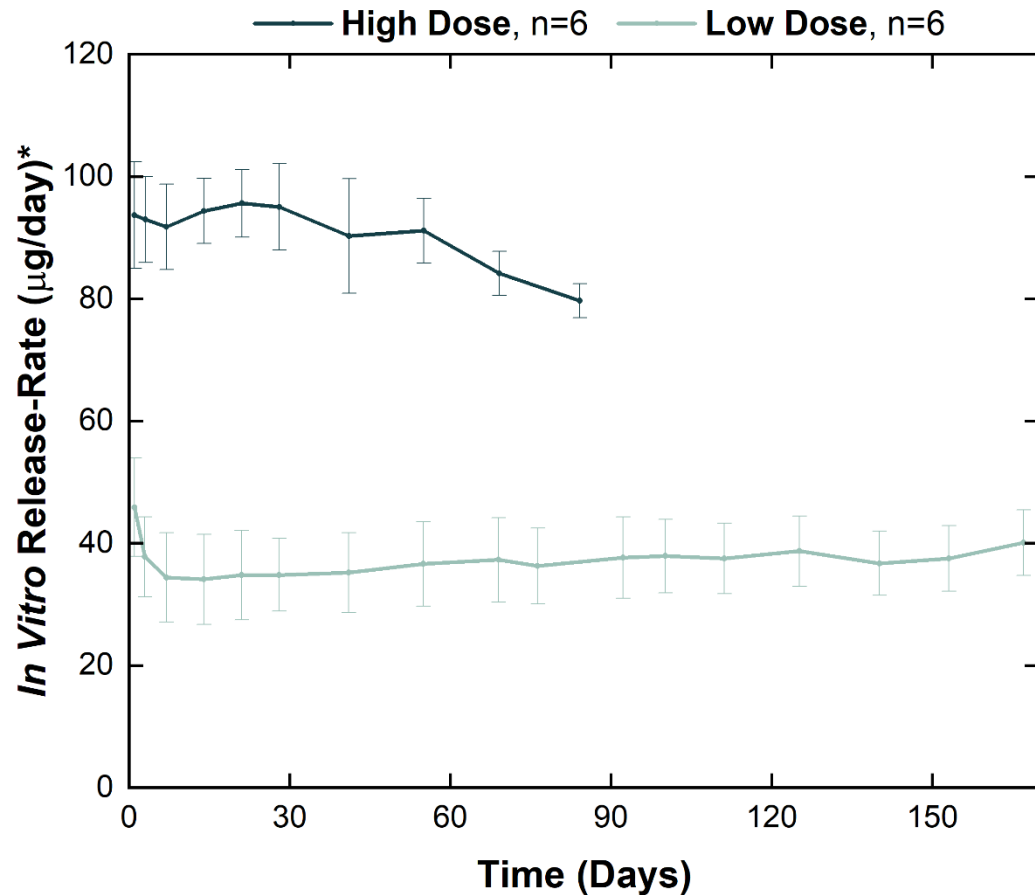
NanoPortal™:

How it Works...

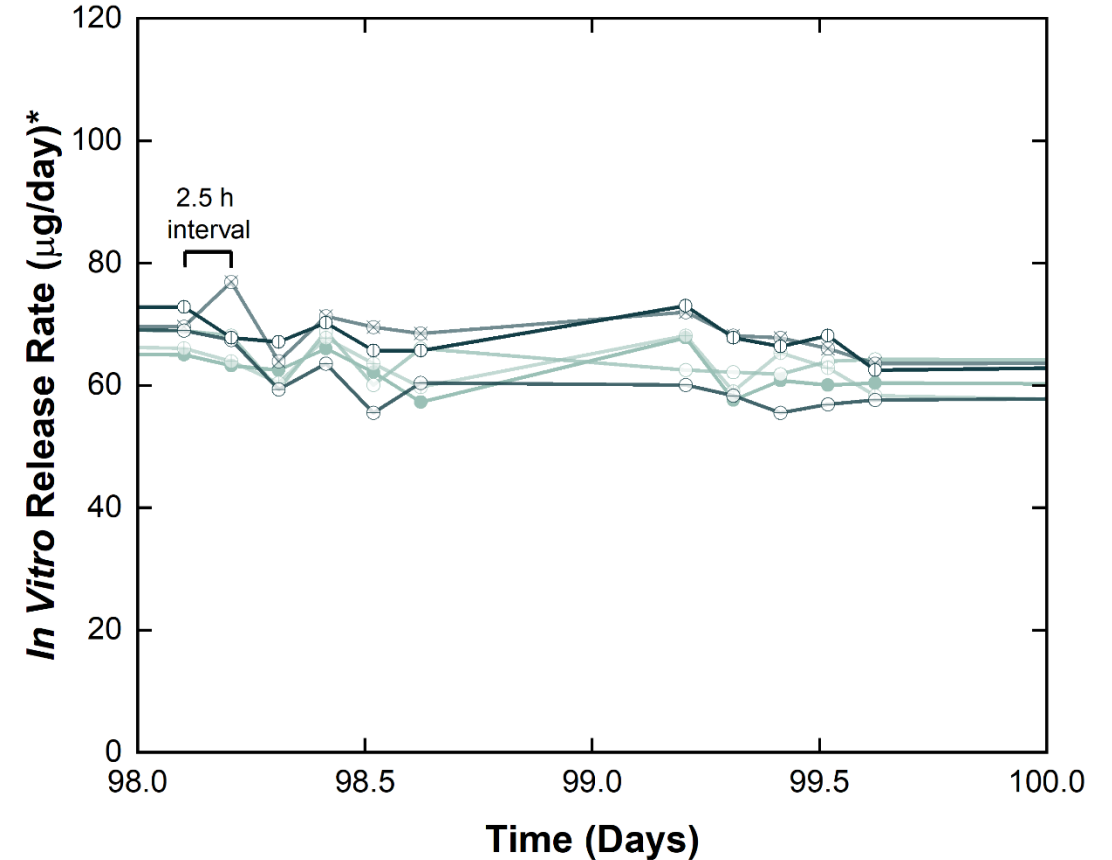
By precisely adjusting nanotubes to molecule size, interactions between drug and nanotube walls can result in desirable release profiles over time, including **near constant release**



NanoPortal delivers near-constant / minimally-fluctuating drug release



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



Fluctuations during each 2.5-hour interval are within measurement error

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.

NanoPortal™ is a Platform Technology

Broad Potential Application Can Support Portfolio of New Drug Implants

» Minimized Implant Size

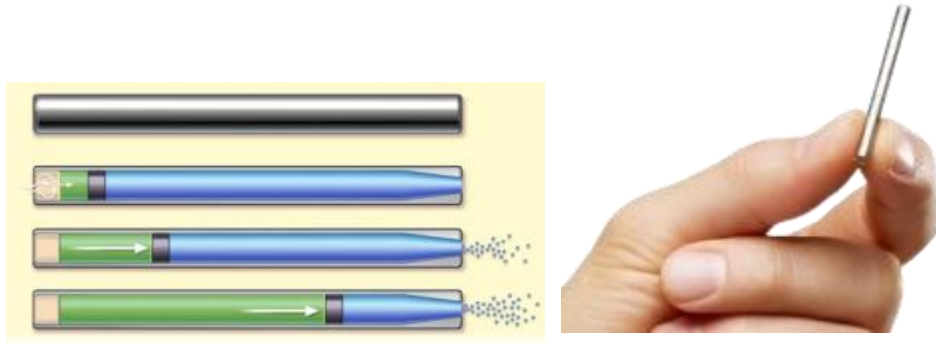
» Extendable Implant Duration

» Tunable Delivery Rate

» Tunable Delivery Profile

NanoPortal implant technology designed to avoid earlier device challenges

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**

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

Vivani Lead Program

NPM-115

High-Dose Exenatide Implant for Chronic Weight Management

Targeting the Rapidly Growing GLP-1 RA Market

Lead Program NPM-115:

Development of 6-Month Exenatide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Chronic Weight Management in Obese or Overweight Patients

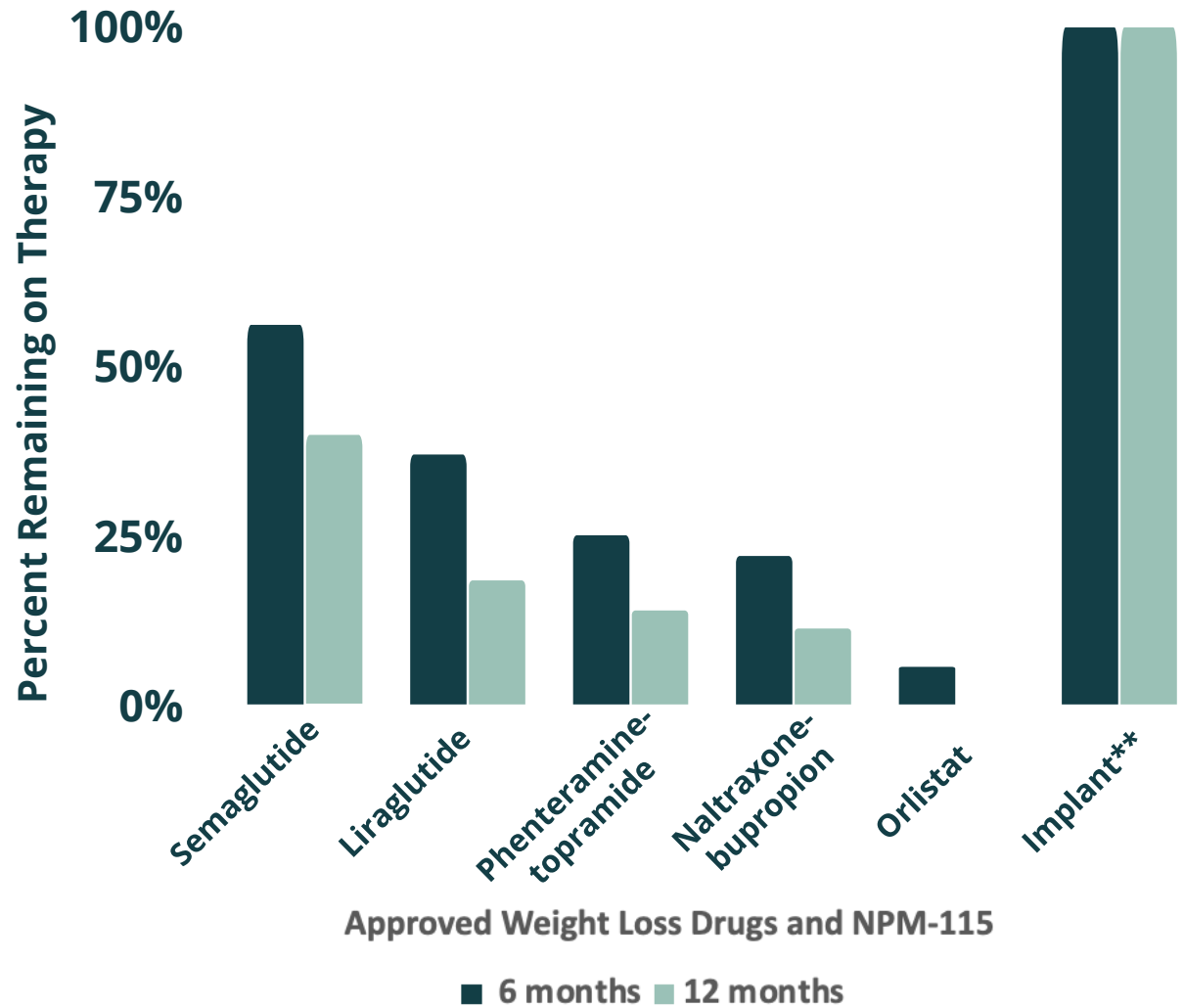
- Tremendous unmet medical need in Obesity¹:
 - 764M people living with obesity
 - 15M (2%) taking an anti-obesity medication
- GLP-1 monotherapy may provide adequate weight loss for the majority of patients²
- Preclinical data with NPM-115 has demonstrated similar magnitude of weight loss for exenatide 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

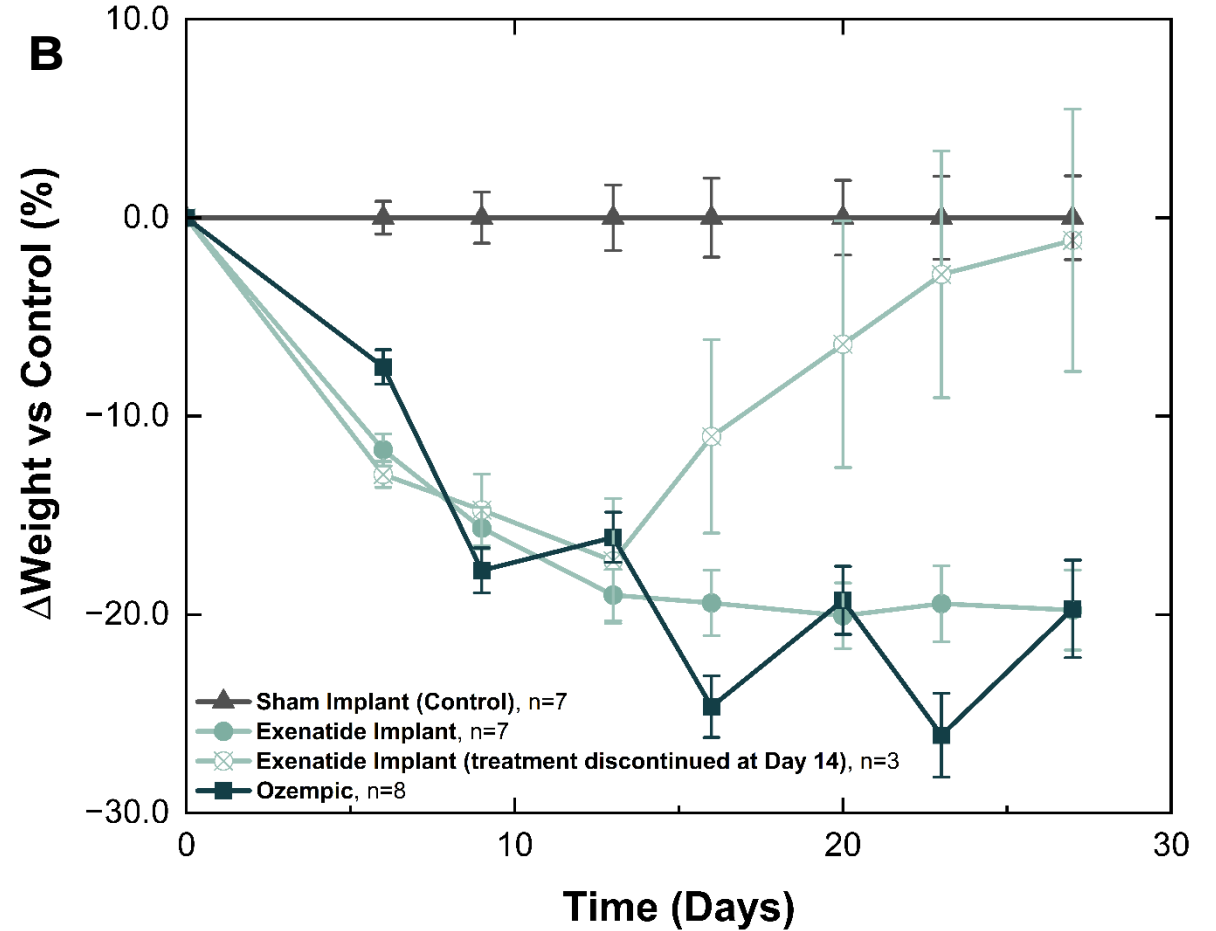
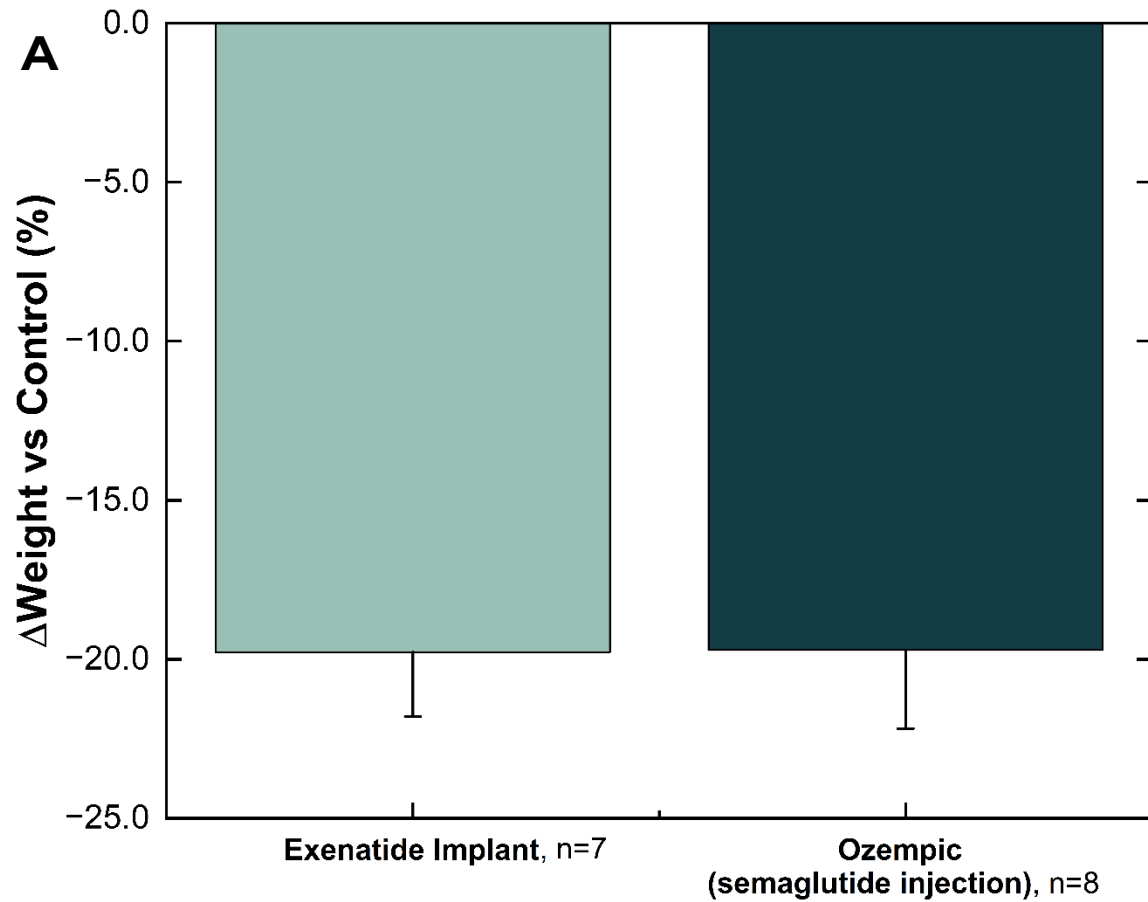
Large Retrospective Cohort Study* (N=1,911)



* Published in Obesity, December 8, 2023

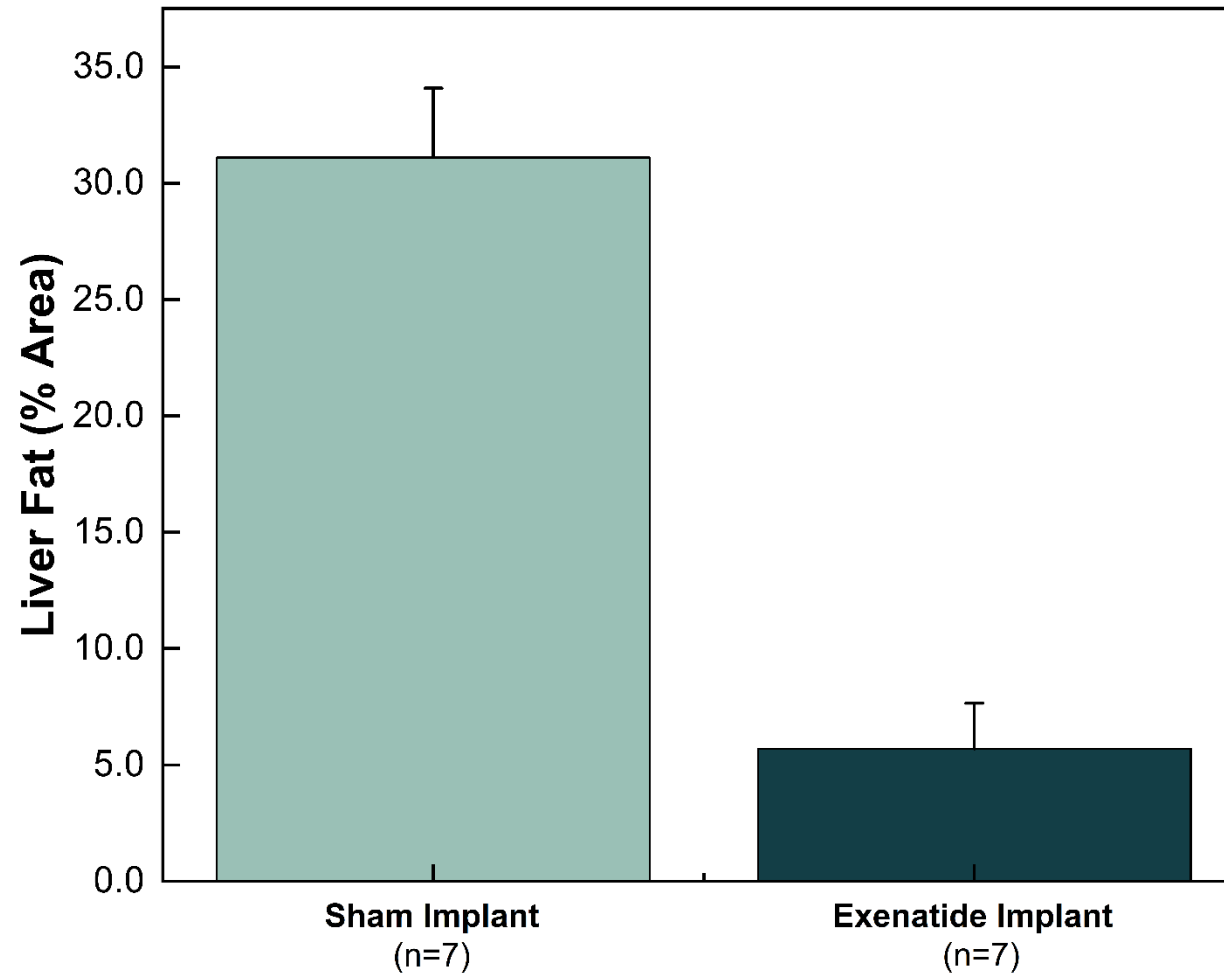
** NPM-115's exenatide implant was not included in the published study, assumes one implant replaced after six months. Currently under development, designed to enable 100% adherence, not approved in any market.

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



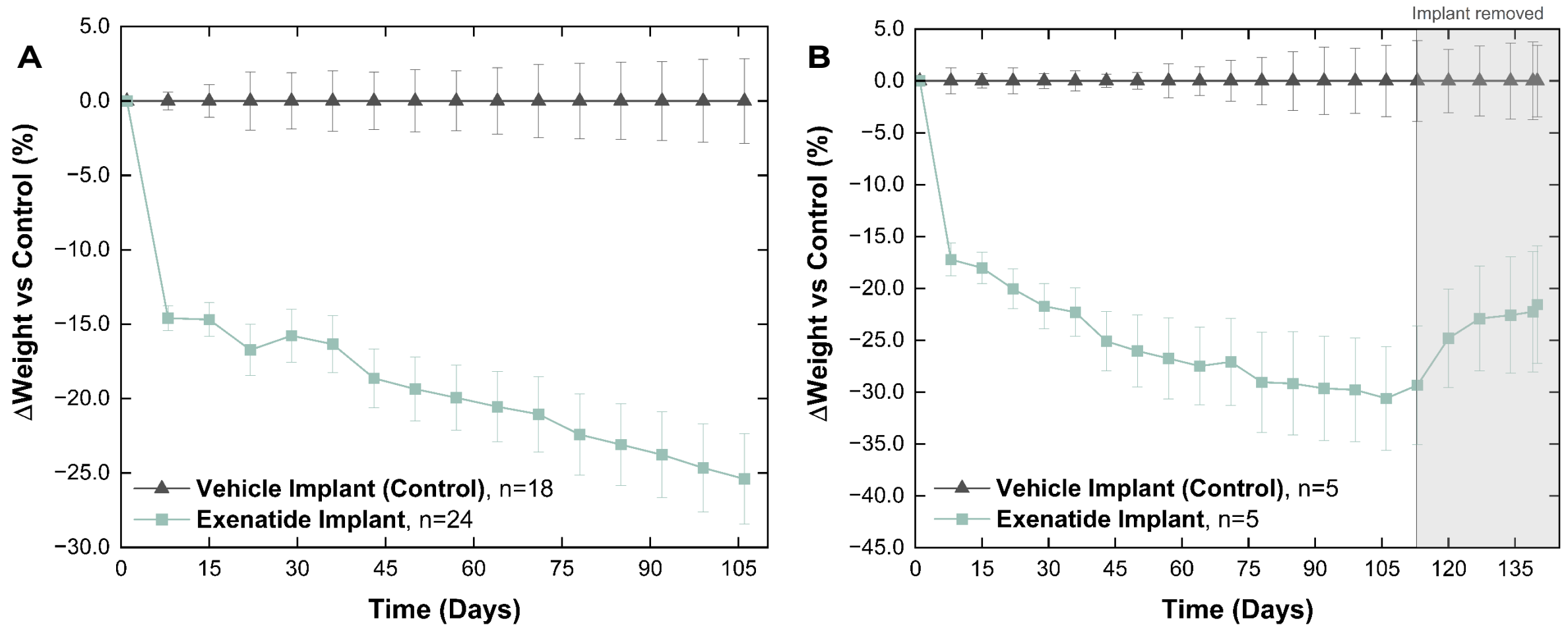
Weight loss in high fat diet-induced obese mice. (A) % weight change from baseline for a single administration of exenatide implant (~530 nmol/kg/day) vs weekly Ozempic injections (semaglutide, 2,700 nmol/kg/week), corrected to control (sham implant) at 28 days; **(B)** % weight change from baseline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

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



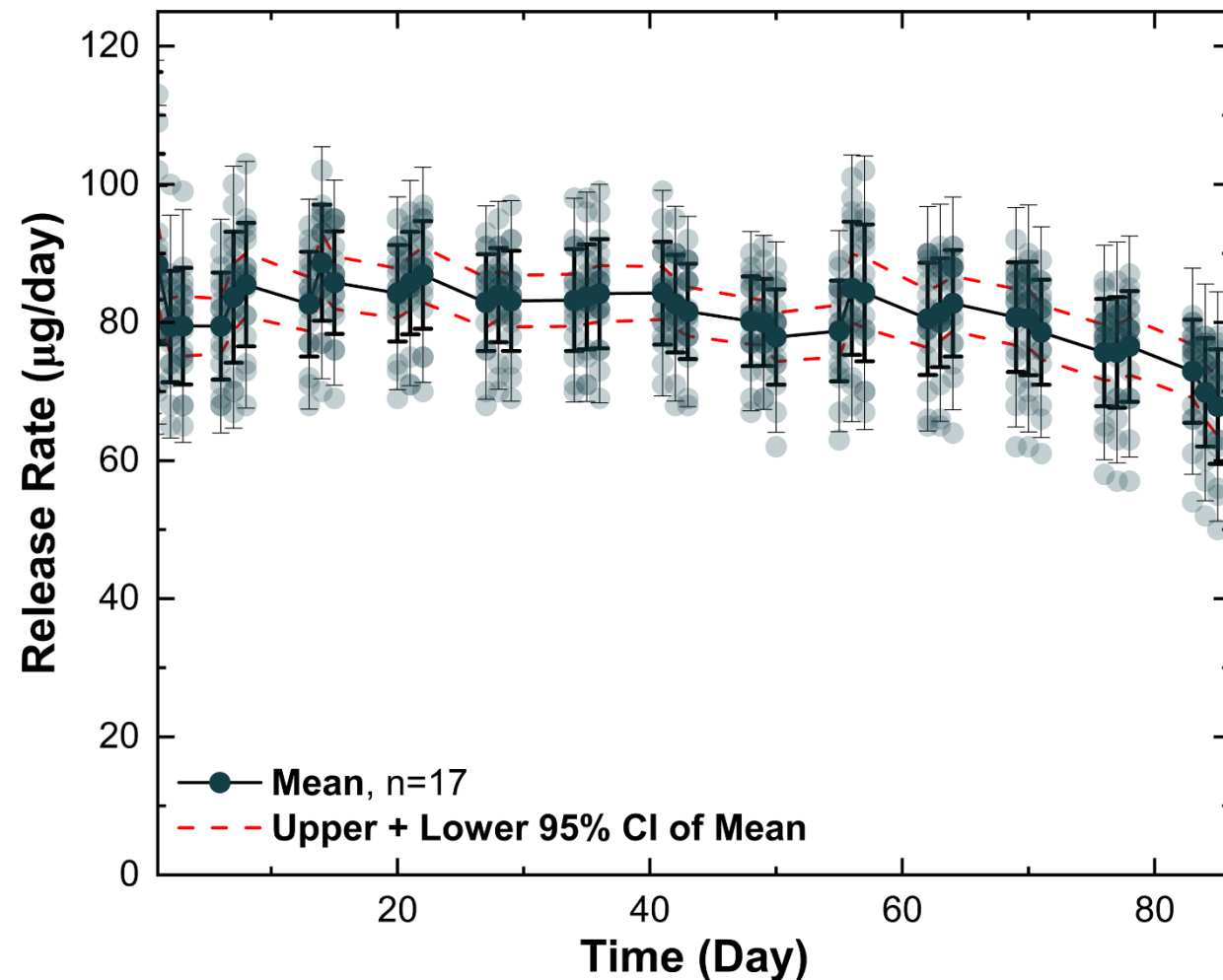
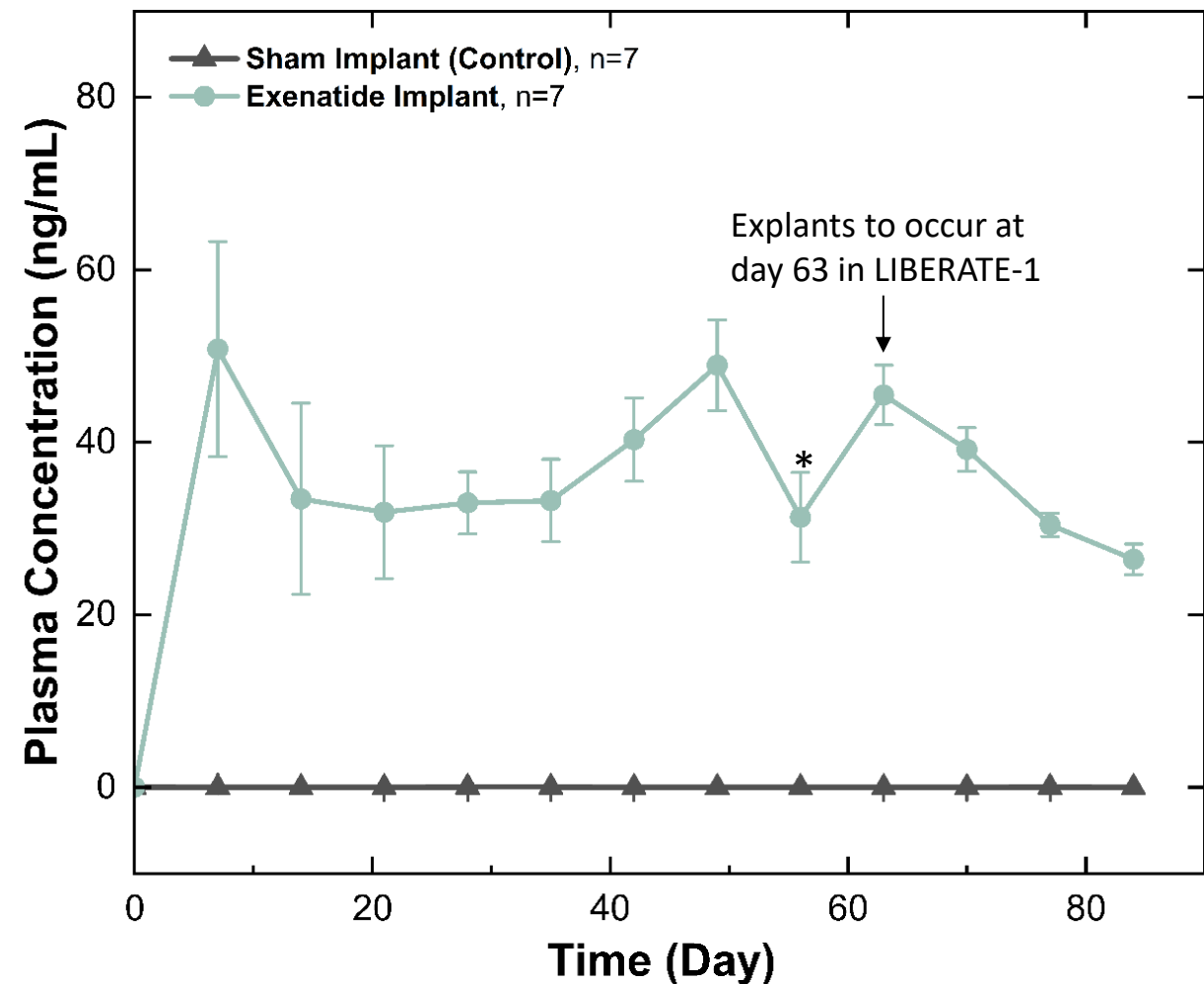
Liver fat reduction in high fat diet-induced obese mice. Liver fat % area for exenatide implant vs sham implant 12 weeks after a single administration. Liver fat % area is calculated using Oil Red O (ORO) staining. Values are mean \pm SE. These results are numerically consistent with a [similar investigation](#) 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 \pm SE.

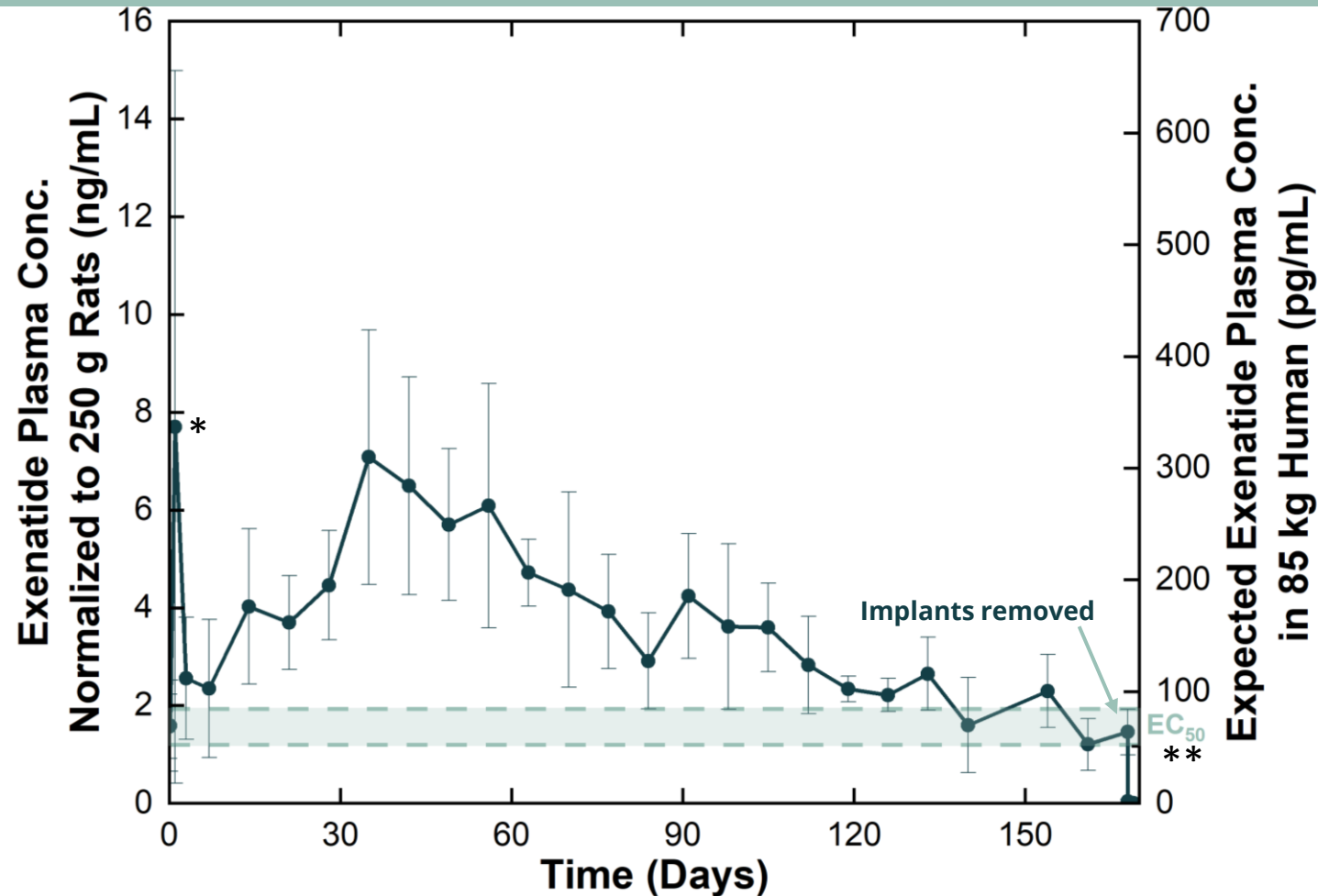
In vivo and *in vitro* performance of 12-week exenatide implant configuration to be studied in LIBERATE-1



***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 \pm SE. *Day 56 values are reported as measured, but a sample handling error at this time point is 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 \pm 1 SD (bold) and \pm 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.

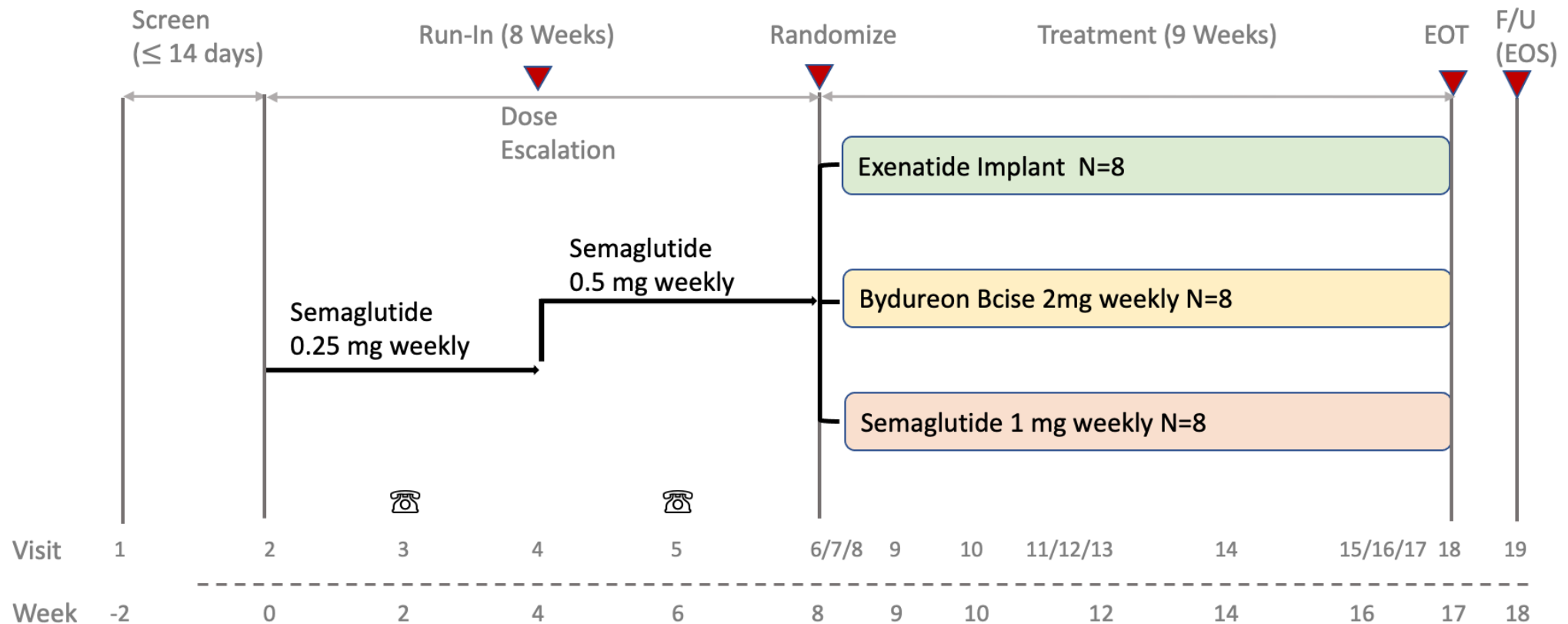
*2 of 6 implants are responsible for higher Day 1 exenatide concentrations which is not expected to occur in the configuration to be used in the clinic.

** 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

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 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	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 NPM-115 clinical program and initiated development of the 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.

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 the NPM-119 program (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

NPM-119

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

- Significant unmet need in Diabetes¹:
 - 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 savings⁴
- 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"

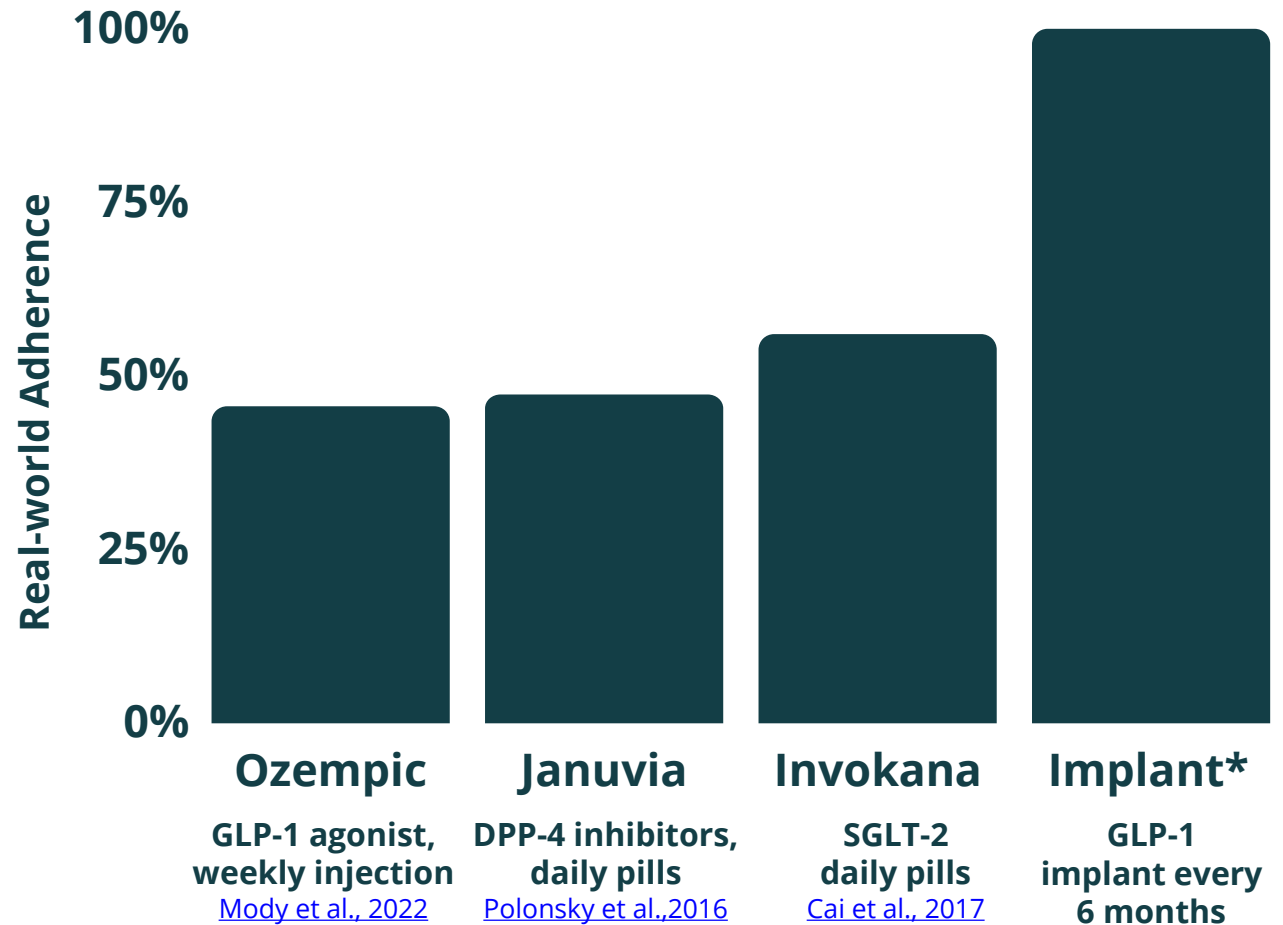
NPM-119* Designed to Enable 100% Adherence through Implant Duration

- 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

Real-World Adherence of Select Drugs

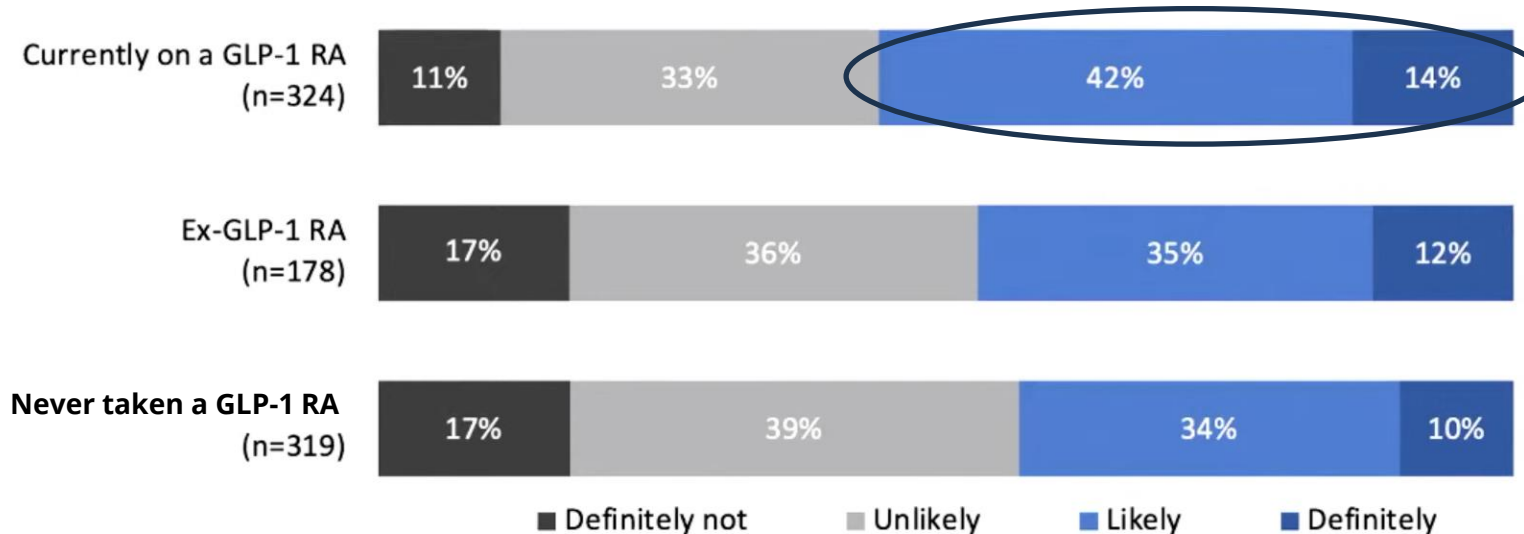


* NPM-119's exenatide implant – under development, designed to enable 100% adherence, not approved in any market

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%)



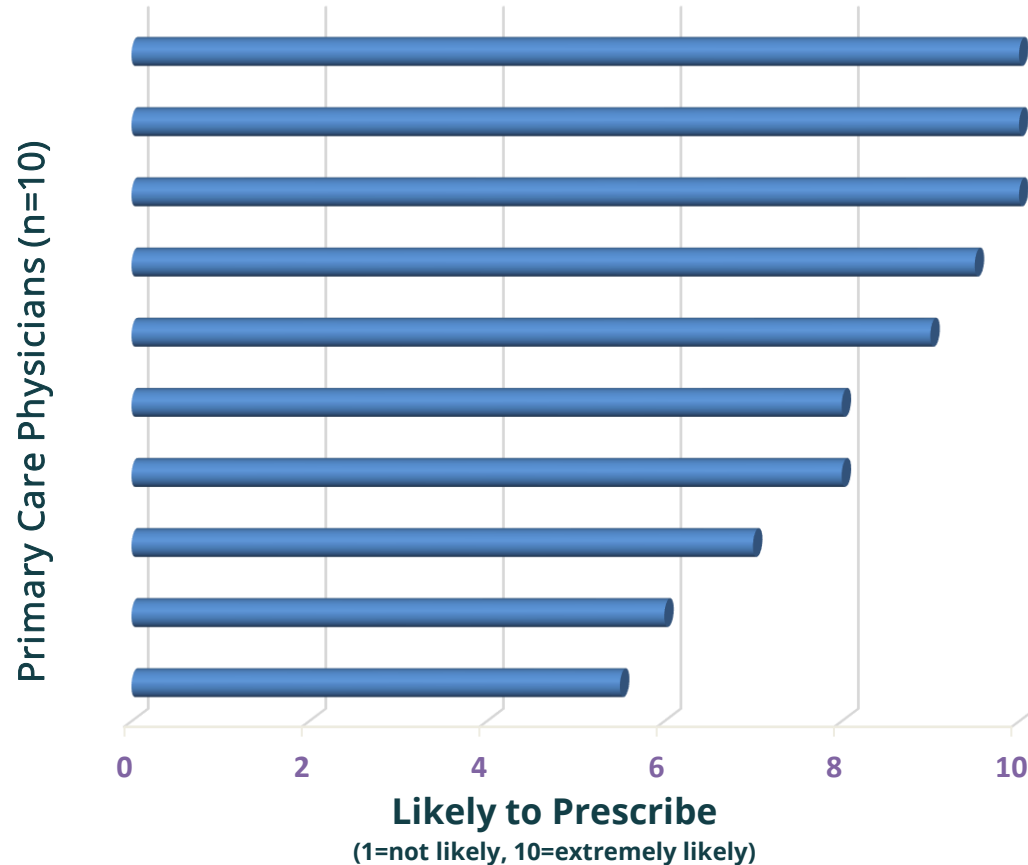
56% of patients responded "likely" or "definitely" to get an exenatide implant if FDA approved, prescriber recommended, and covered by insurance

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**?"

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

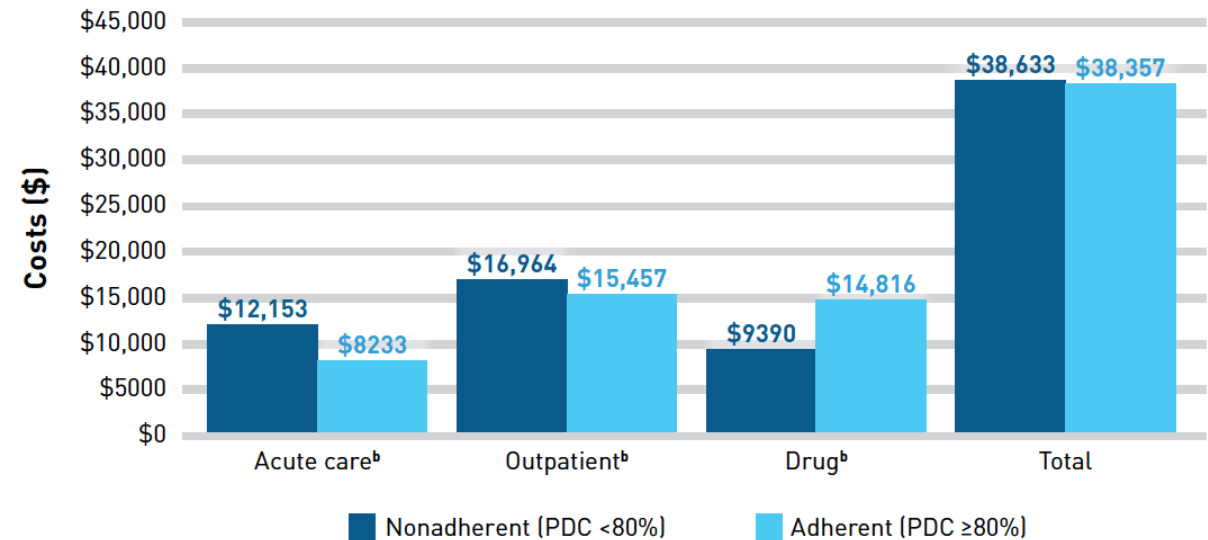
Prescribing Rating, Average 8.3 out of 10

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](#)

NPM-119 Clinical + Regulatory Development Near-Term Plan

Year(s)	Milestone	Status
2024	IND cleared	June 2024

June 13, 2024 – Vivani announced that the FDA cleared 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.

Vivani Medical, Inc.
Financial Information

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>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 24,919	\$ 20,654
Prepaid expenses and other current assets	1,418	2,408
Total current assets	26,337	23,062
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
Total assets	\$ 48,224	\$ 45,797
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 5,784	\$ 5,723
Long term operating lease liabilities	18,616	19,313
Total liabilities	24,400	25,036
Stockholders' equity:	-	-
Total Common Stock, APIC & Other Comp Gain	133,657	119,199
Accumulated deficit	(109,833)	(98,438)
Total liabilities and stockholders' equity	\$ 48,224	\$ 45,797

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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