



Nasdaq: VANI

www.vivani.com

Vivani Medical, Inc.

Guaranteed Adherence. Better Outcomes.

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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



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 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 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

Vivani Medical, Inc.

1

An innovative, biopharmaceutical company developing a portfolio of miniature, long-term, drug implants to treat chronic diseases. Our NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability.

2

Lead programs NPM-115 and NPM-119 are miniature, six-month, GLP-1 (exenatide) implants under development for the treatment of chronic weight management in obese or overweight patients and type 2 diabetes, respectively.

3

NPM-139 (semaglutide implant) is also under development for chronic weight management with the added potential benefit of once-yearly administration.

4

Vivani is well-positioned to advance NPM-115 and NPM-119 towards potentially transformational milestones in 2024.

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			>\$50B
	Human Type II Diabetes	NPM-119 exenatide			>\$20B
	Human Obesity	NPM-139 semaglutide			>\$50B
	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
JP Morgan analyst Richard Vossler estimates GLP-1 Market reaches \$71 billion by 2032 (9/11/2023). We assume >\$20B for type 2 diabetes and >\$50B for chronic weight management in obese or overweight patients

** In Partnership with Okava Pharmaceuticals, Inc.



Drug Implants

Proprietary Platform Technology

NanoPortal™:

Innovative Delivery Technology



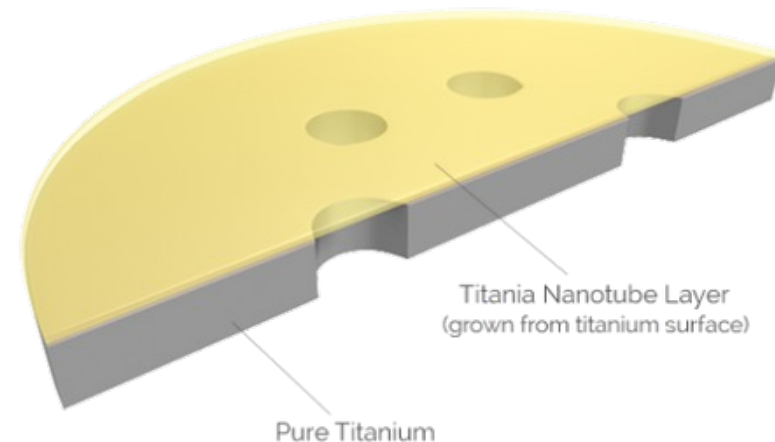
Designed to assure adherence



Minimally-fluctuating and tunable delivery profiles



Potential application with many molecular types

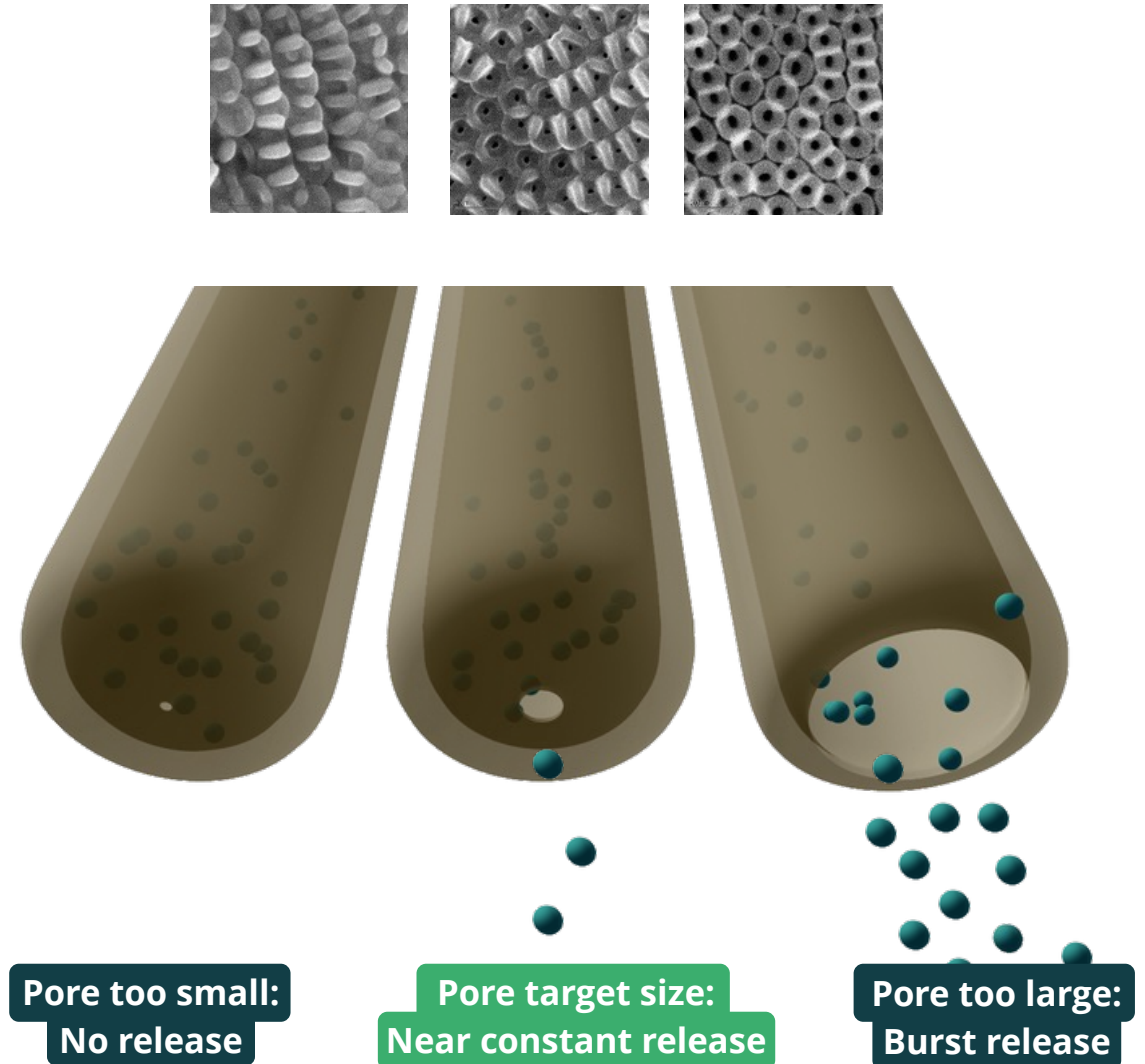


**Nanotube
Membrane**

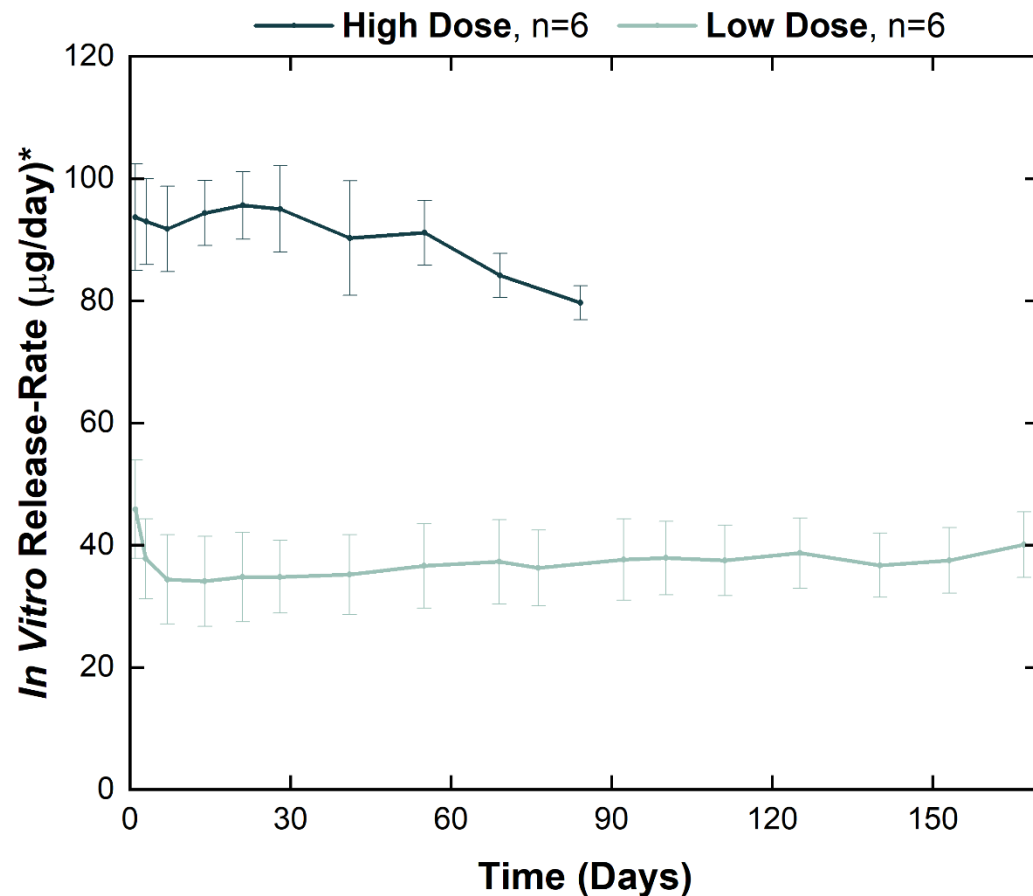
NanoPortal™:

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**



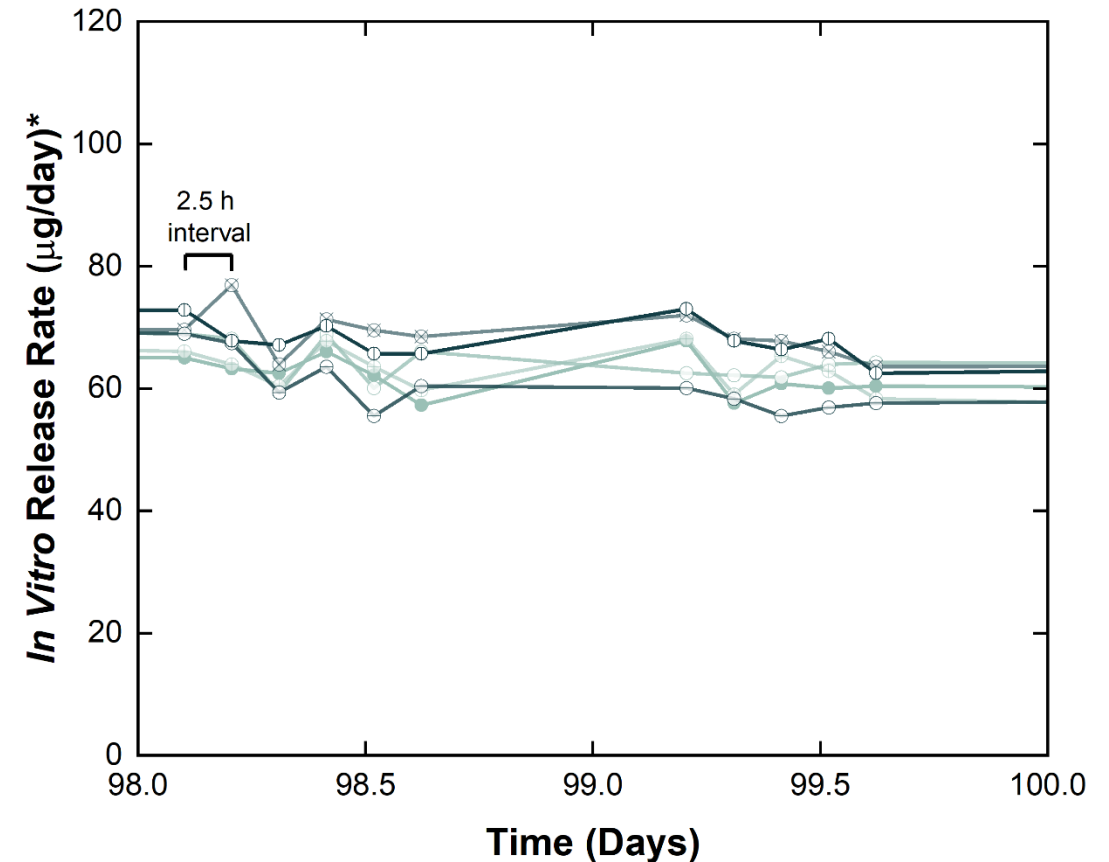
Near-constant and minimally-fluctuating release



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

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 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
- Preliminary 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

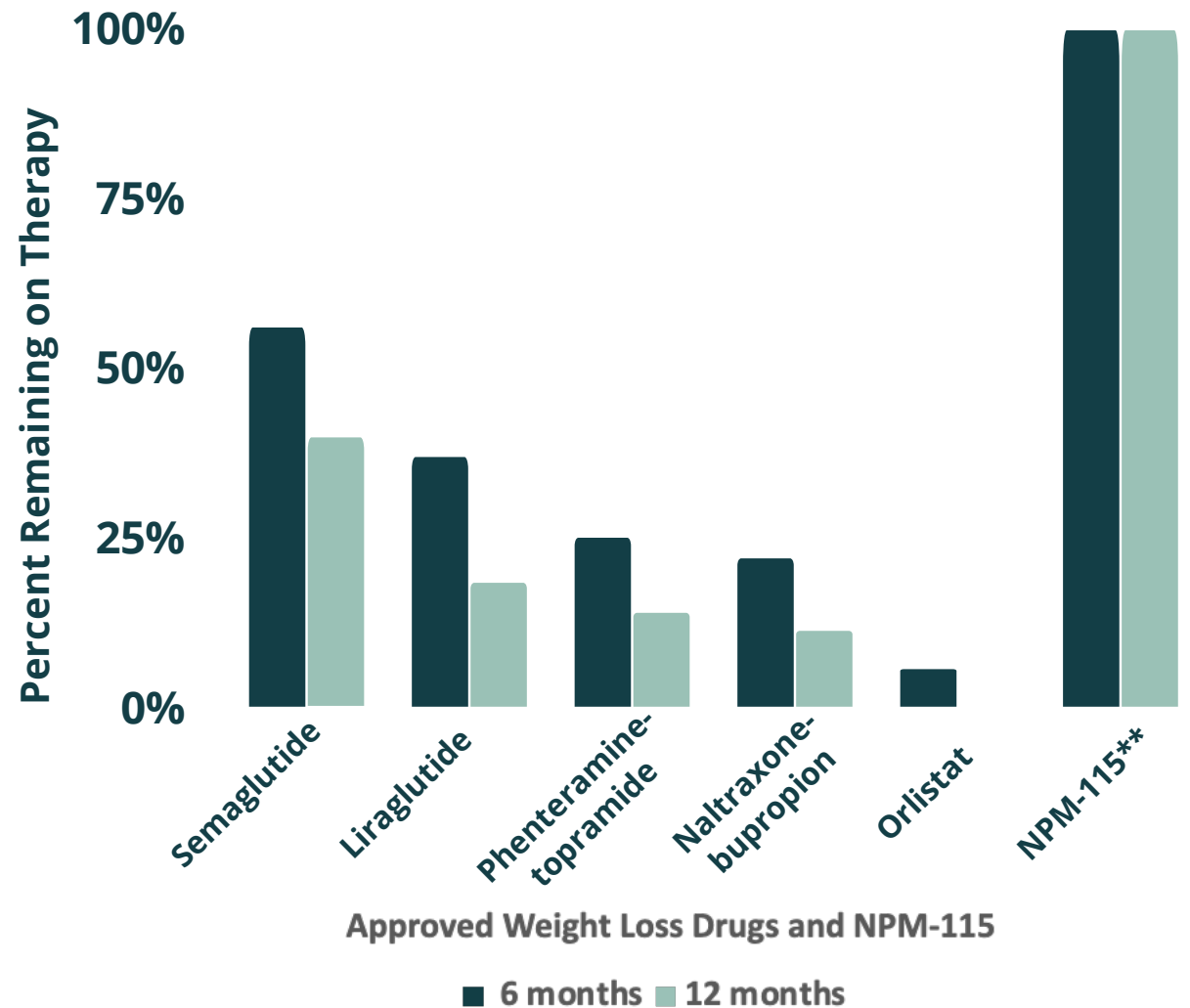
Weight Loss Medicines Associated With Adherence Challenges

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

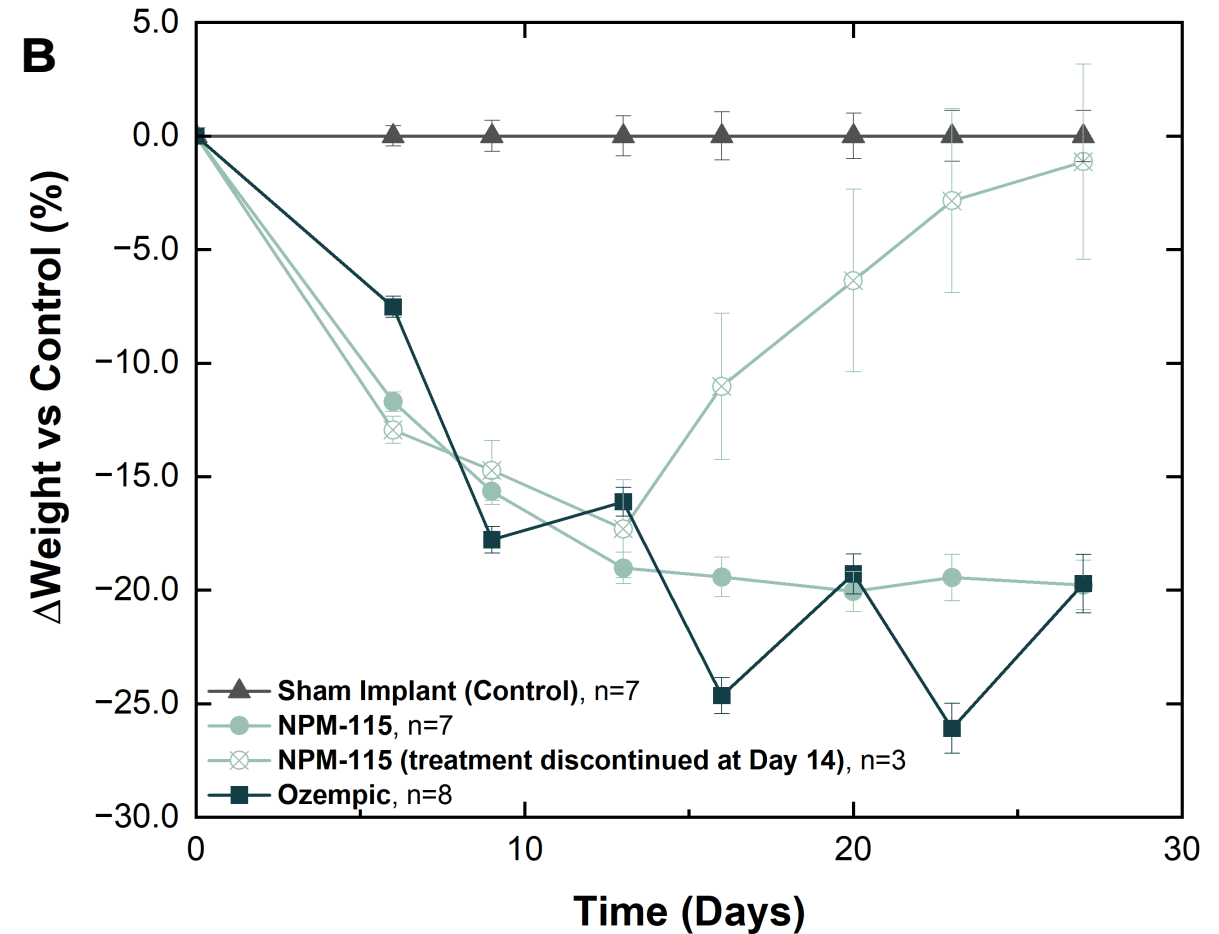
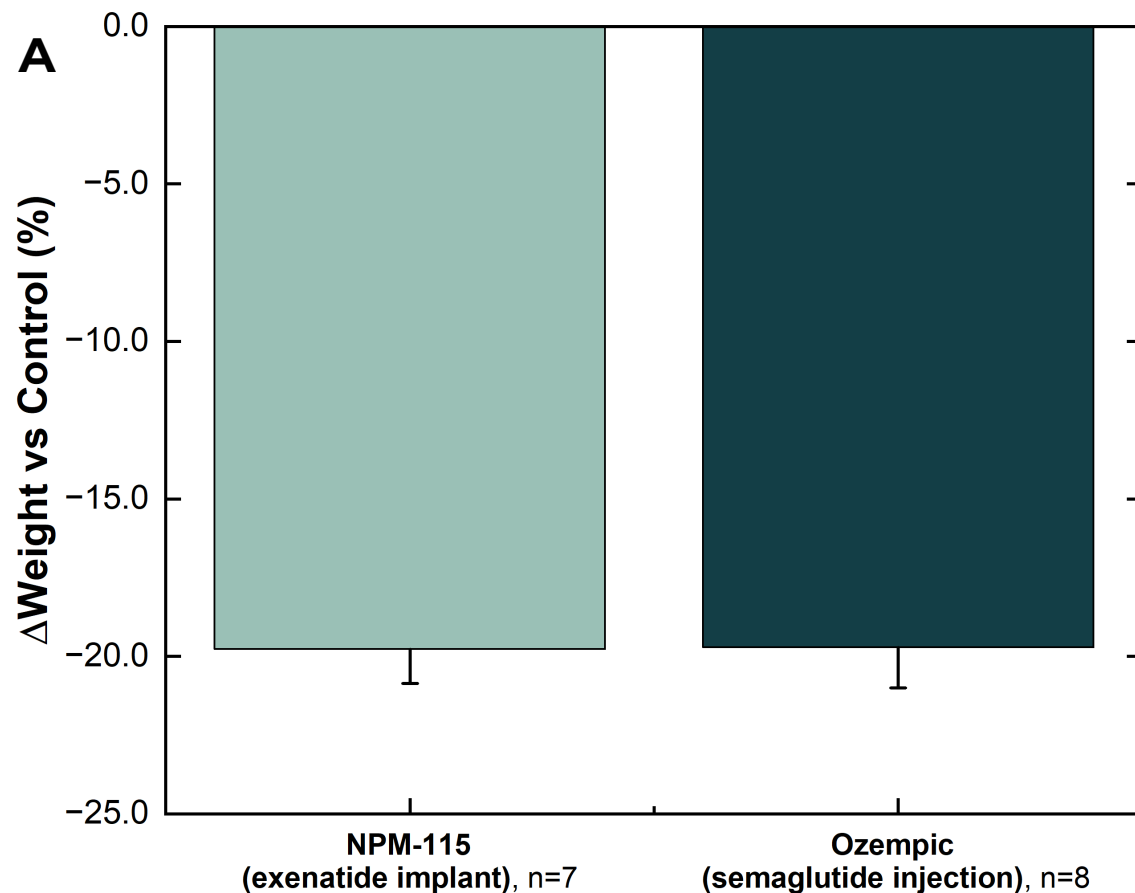
- The remaining opportunity for an additional 60% improvement in persistence is significant and will translate to improved patient outcomes
- NPM-115 (exenatide implant) is designed to guarantee adherence for 6 months / implant

* 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.

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

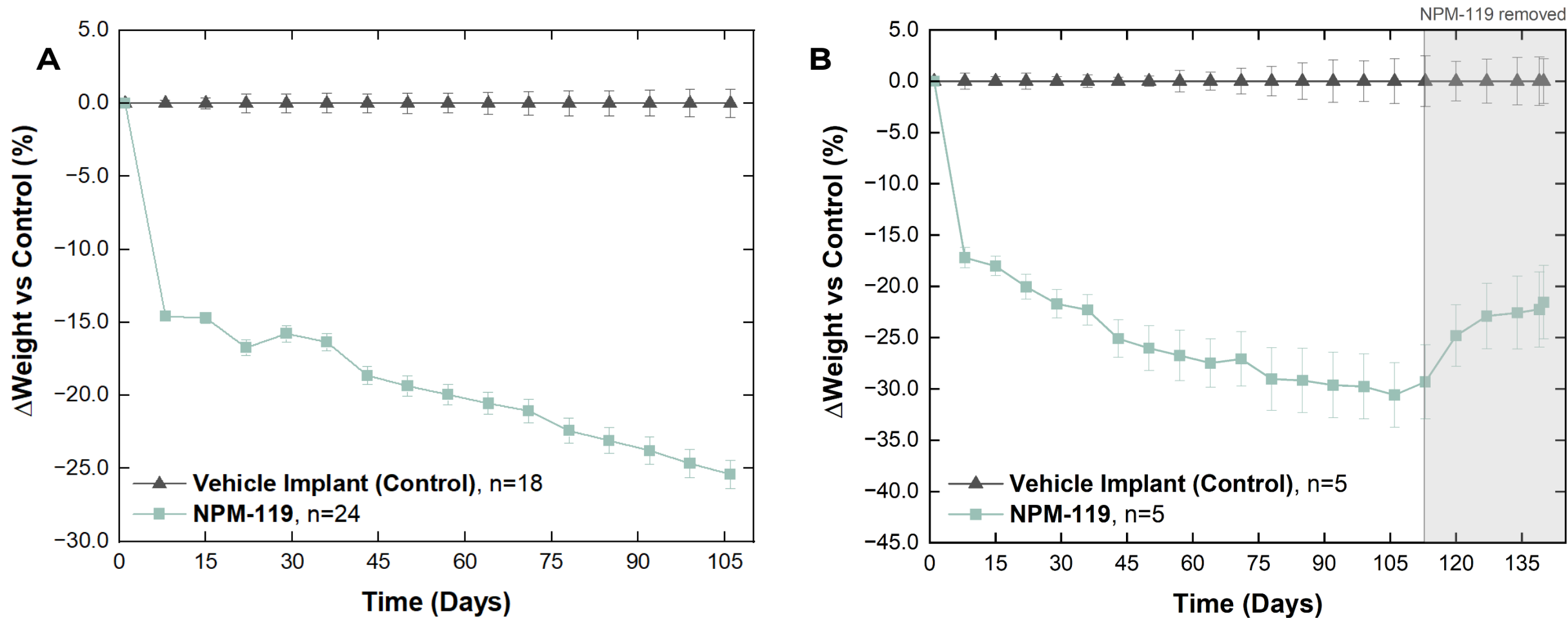


NPM-115 is associated with comparable weight loss to semaglutide in preclinical studies



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.

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 studies	February 2024
2024	Submit IND filing to FDA for First-In-Human study	Expected 2024

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).

2024 – Planned submission of an Investigational New Drug Application to support the initiation of a First-in-Human trial of NPM-115 for the treatment of chronic weight management in obese or overweight patients.

Vivani Lead Program

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 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

NPM-119 Implant and Applicator



Current Drug Adherence Challenge

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

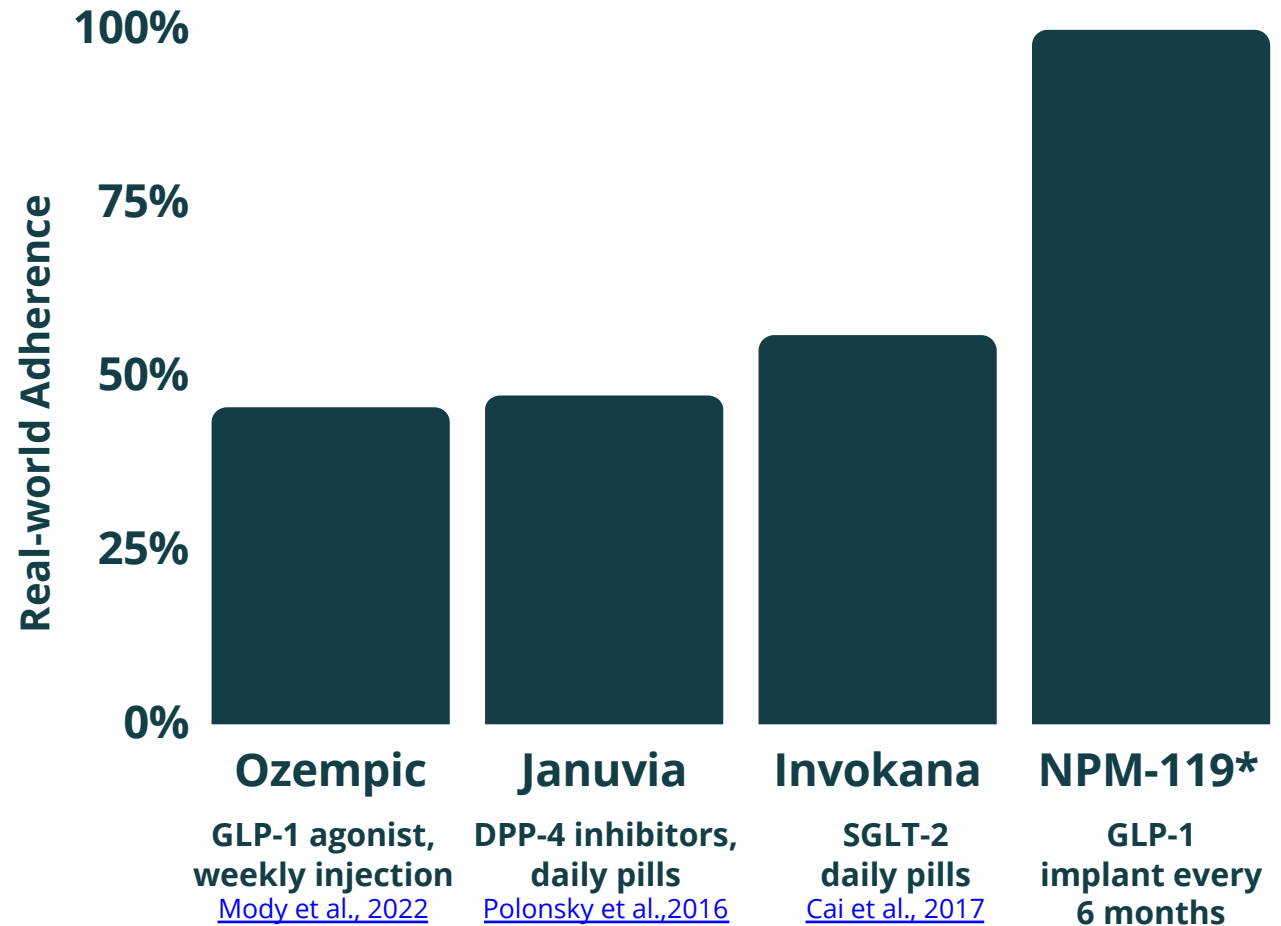
NPM-119* Designed to Enable 100% Adherence through Implant Duration

- 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's¹ 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

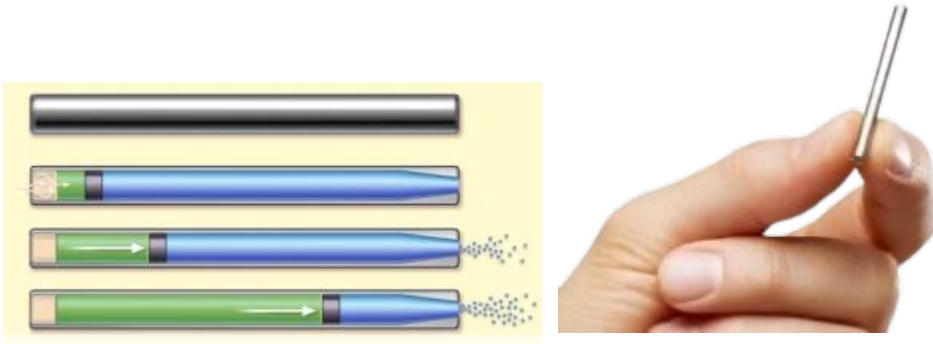
- 2014** – Intarcia signed ITCA 650 deal with Servier (excluding US + Japan) \$171M up-front, \$880M milestones, and double-digit royalties
 - Financings valued Intarcia as high as \$4.0B (2017); Intarcia's lead program was ITCA 650
- 2016** – Intarcia filed initial ITCA 650 New Drug Application (NDA)
- 2017** – FDA issued the first ITCA 650 CRL² (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 unanimously recommends against the approvability of ITCA 650 due to concerns about safety risks linked to irregular and uncontrolled exenatide release

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 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)



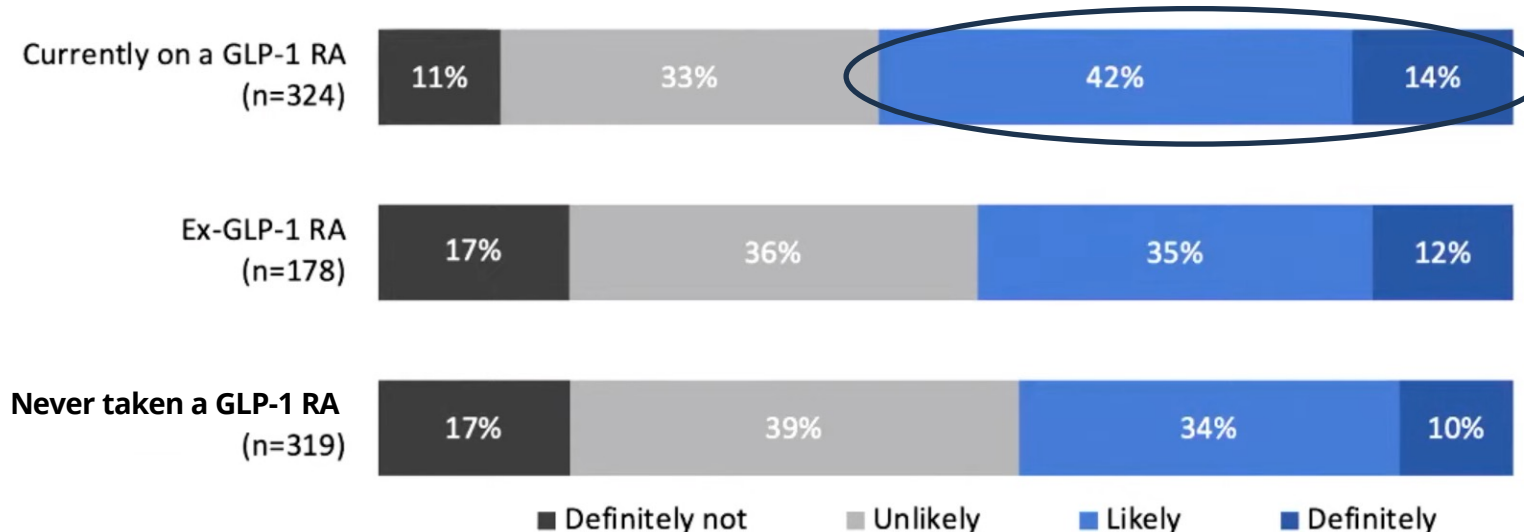
- **Minimally fluctuating drug release** profile observed in pre-clinical studies
- **Smaller Device** (2.2mm x 21.5mm)
- Insertion using **smaller 11-gauge needle**

Patient market research indicates strong market 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

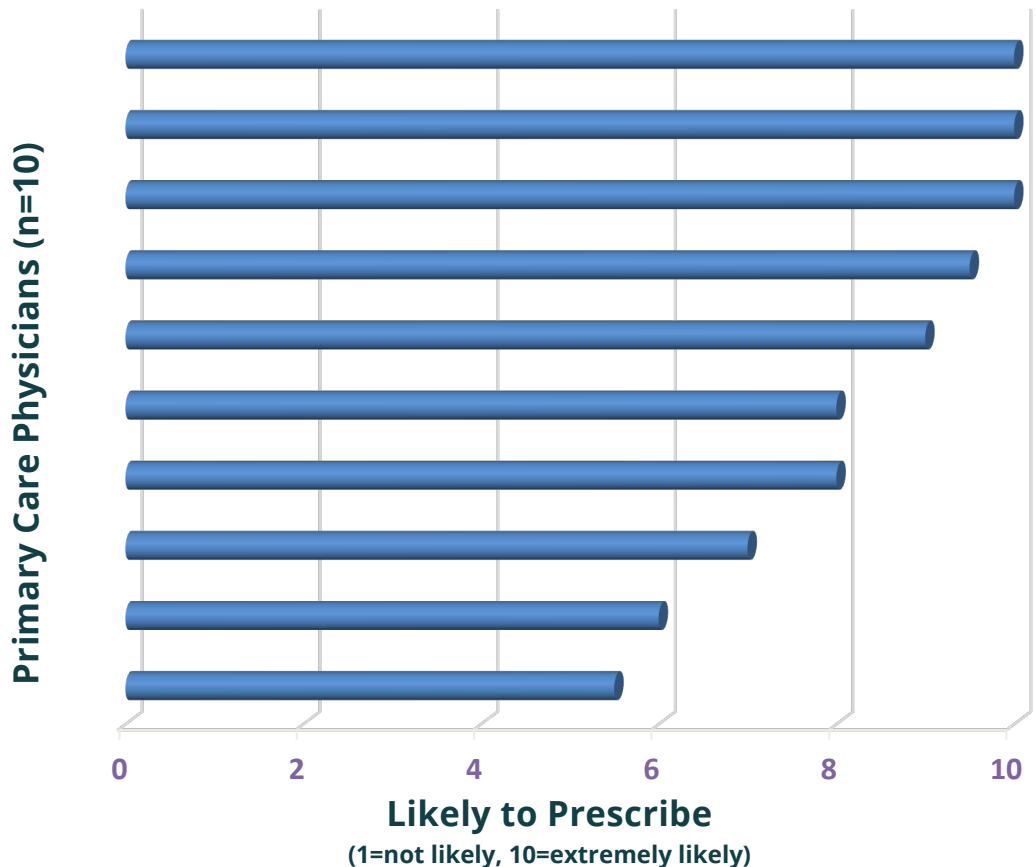
Our question, after showing an image of the device and a description* of how it would be used, was:
"Assuming it was approved by the FDA, your doctor suggests it, and insurance coverage is not an issue, how likely would you be to get and use the **implant with exenatide**?"

dQ&A

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

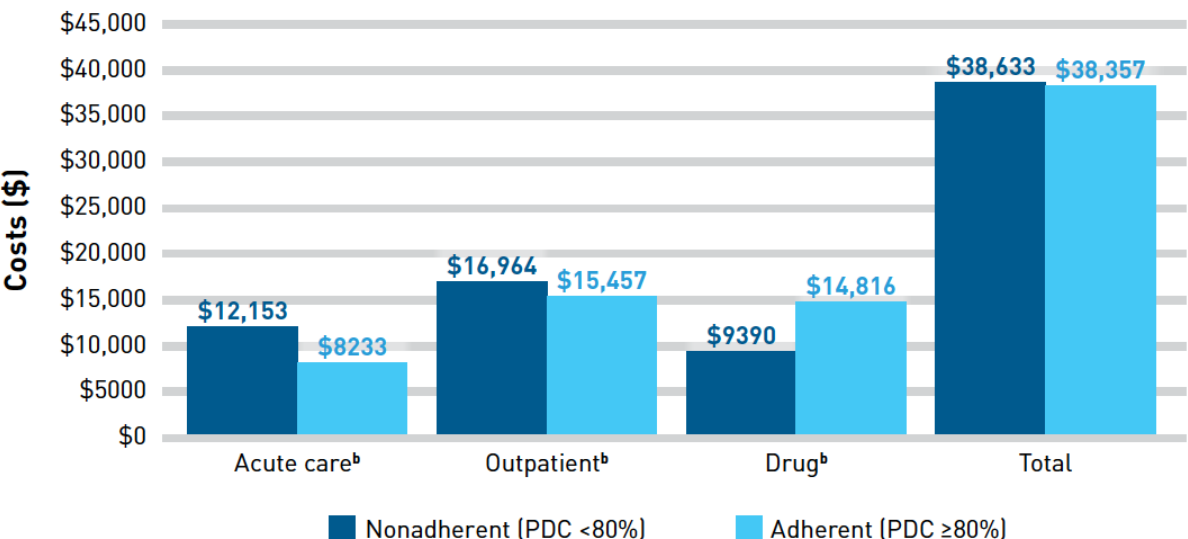
Prescribing Rating, Average 8.3 out of 10

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?



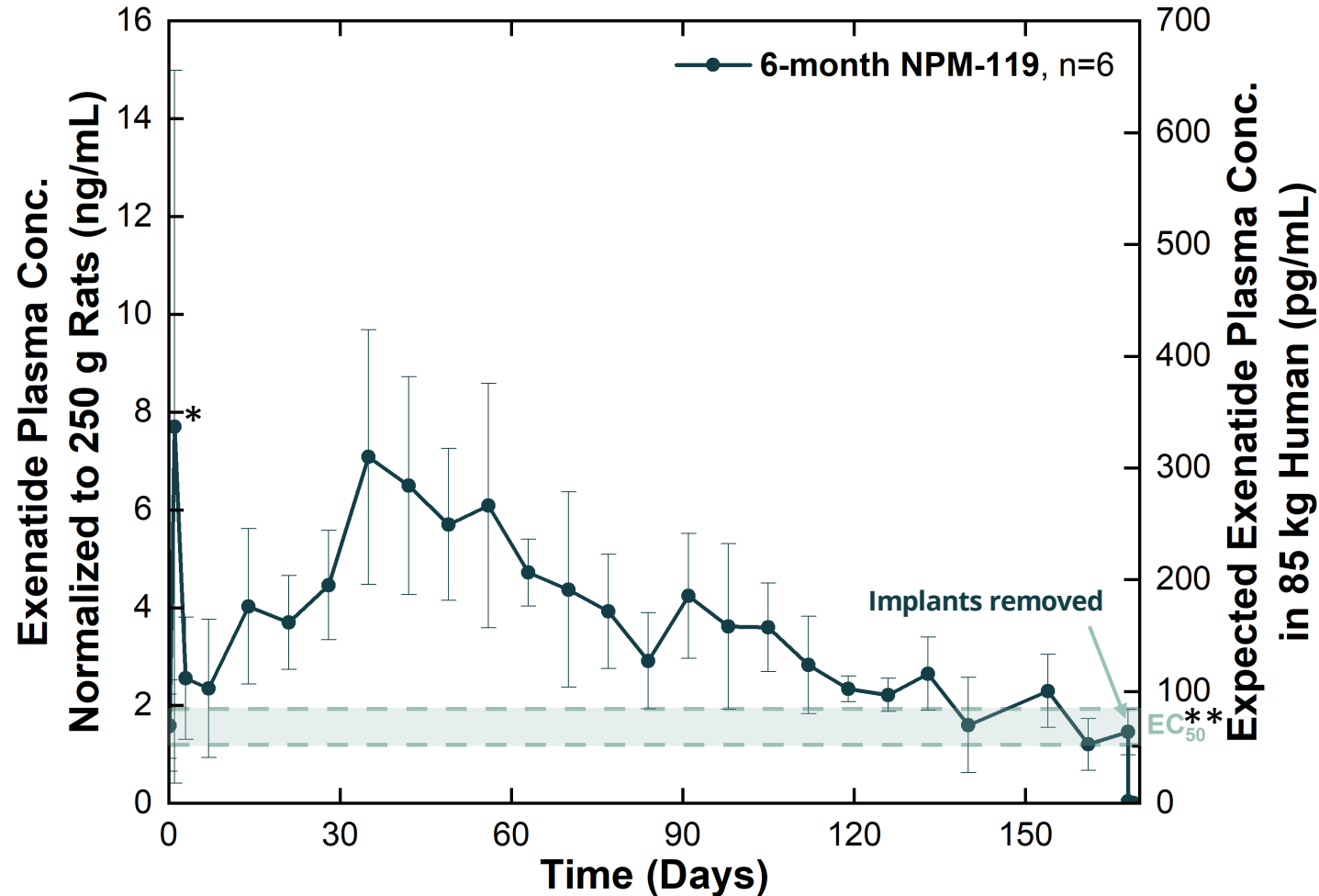
Adherence = Lower Acute Care & Outpatient Costs

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



[Curtis et al., 2017](#)

6-Month NPM-119 preclinical proof-of-concept achieved



Pharmacokinetics of 6-month NPM-119 in male Sprague-Dawley rats

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 and Regulatory Pathway

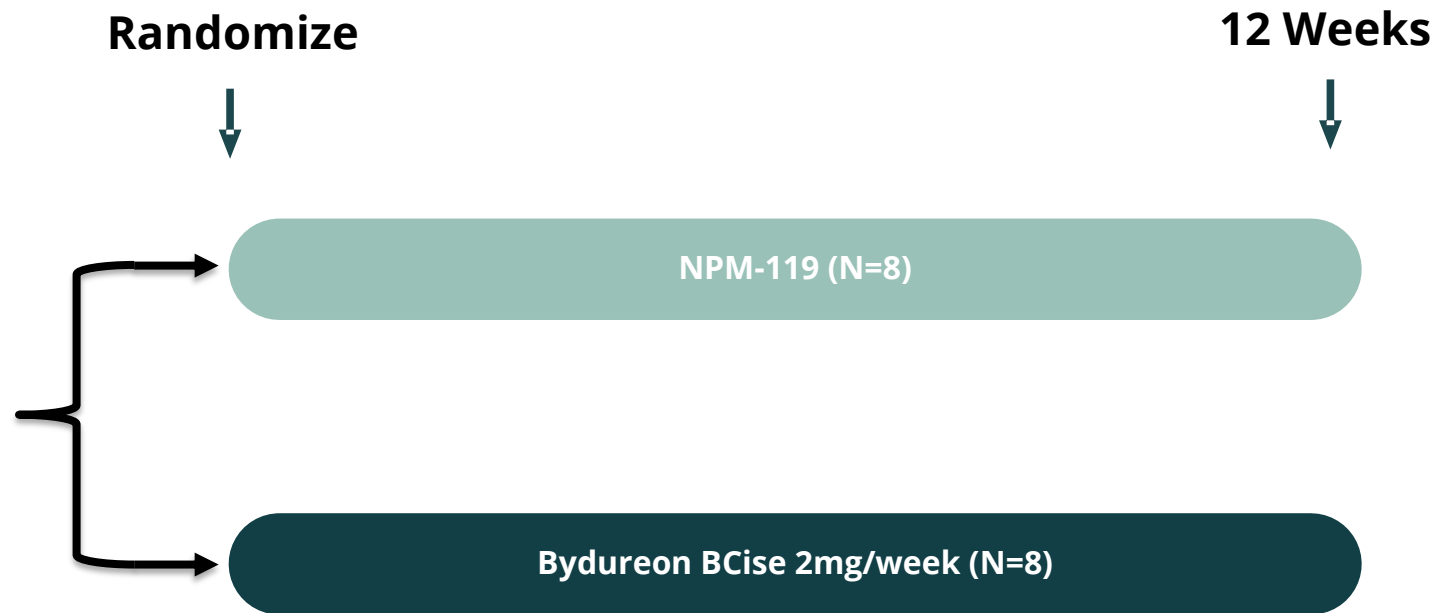
Proposed First-in-Human Trial: LIBERATE-1

Primary Objectives: Safety/tolerability assessment and full PK characterization

Glycemic control (HbA1c) and weight will also be assessed

Key Inclusion/Exclusion Criteria

- T2DM and HbA1c <8.5%
- 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



NPM-119 Clinical + Regulatory Development

Near-Term Plan

Year(s)	Milestone	Status
2023	IND filed to support First-in-Human (LIBERATE-1) clinical study	July 14, 2023
2023	FDA provided Clinical Hold letter	August 18, 2023
2024	Generate/Submit New CMC data to Lift Clinical Hold	2024

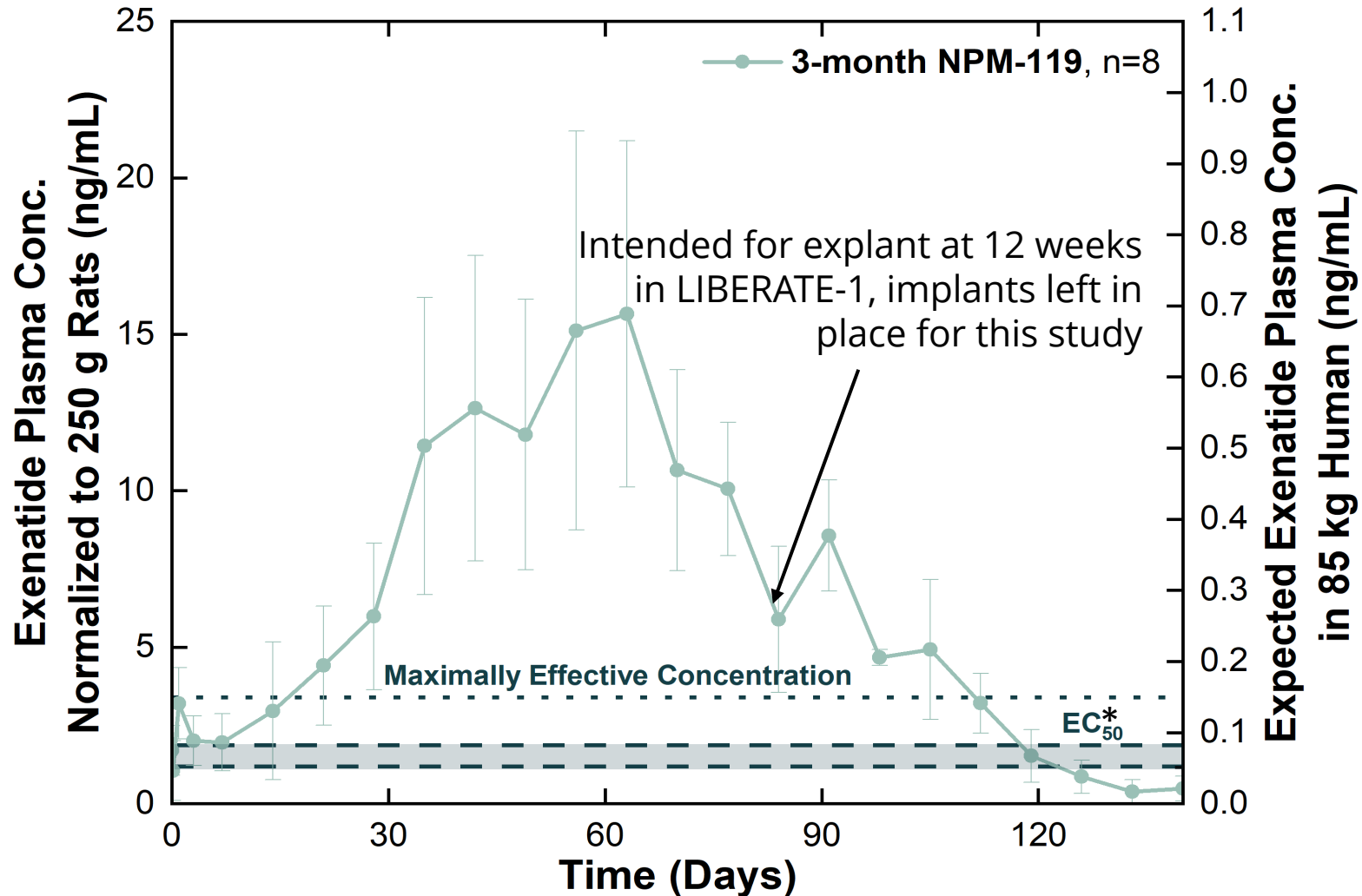
July 14, 2023 – Vivani submitted an Investigational New Drug to support a proposed First in Human study also known as LIBERATE-1 to explore the full pharmacokinetic profile of NPM-119 in patients with type 2 diabetes.

August 18, 2023 – FDA provided a Clinical Hold on the proposed LIBERATE-1 study primarily due to insufficient Chemistry, Manufacturing and Controls (CMC) information.

2024 - Vivani continues to generate the requested CMC information and remains actively engaged in discussions as part of its efforts to lift the Clinical Hold and enable the expeditious initiation of LIBERATE-1. Discussions with FDA to resolve the clinical hold are ongoing.

Vivani currently expects to submit the requested CMC information to the FDA in the first half of 2024.

12-Week NPM-119 PK in Rats



Pharmacokinetics of 3-month NPM-119 in male Sprague-Dawley rats

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

* 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 .

Vivani Medical, Inc.

Financial Information

Vivani Medical, Inc.

Q3 2023: P&L Statement

Condensed Consolidated Statements of Operations (unaudited)

In Thousands, except per Share Data	3 Months Ended		9 Months Ended	
	Sep. 30, 2023	Sep. 30, 2022	Sep. 30, 2023	Sep. 30, 2023
Operating expenses:				
Research and development, net of grants	\$ 4,441	\$ 3,859	\$ 12,260	\$ 9,742
General and administrative	2,703	1,585	8,488	3,709
Total operating expenses	7,144	5,444	20,748	13,451
Loss from operations	(7,144)	(5,444)	(20,748)	(13,451)
Other income (expense), net	362	6,867	1,122	6,846
Net income/(loss)	\$ (6,782)	\$ 1,423	\$ (19,626)	\$ (6,605)
Net income/(loss) per common share – basic	\$ (0.13)	\$ 0.04	\$ (0.39)	\$ (0.18)
Net income/(loss) per common share – diluted	\$ (0.13)	\$ 0.04	\$ (0.39)	\$ (0.18)
Weighted average common shares outstanding – basic	50,837	37,965	50,757	37,712
Weighted average common shares outstanding – diluted	50,837	38,477	50,757	37,712

Vivani Medical, Inc.

Q3 2023: Balance Sheet

Condensed Consolidated Balance Sheets (unaudited)

<i>In Thousands</i>	<u>Sep. 30, 2023</u>	<u>Dec. 31, 2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 24,821	\$ 45,076
Prepaid expenses and other current assets	5,861	2,452
Total current assets	30,682	47,528
Property and equipment, net	1,134	1,182
Right-of-use assets	20,050	779
Restricted cash	1,366	1,366
Deposits and other assets	87	275
Total assets	\$ 53,319	\$ 51,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current liabilities	\$ 7,433	\$ 6,822
Long term operating lease liabilities	19,679	—
Total liabilities	27,112	6,822
Stockholders' equity:		
Total Common Stock, APIC & Other Comp Loss	118,619	117,094
Accumulated deficit	(92,412)	(72,786)
Total liabilities and stockholders' equity	\$ 53,319	\$ 51,130

Vivani Medical, Inc.

Q3 2023: Cap Table

<i>As of September 30, 2023</i>		
Equity	WAEP*	Number of Shares
Common Stock		51,025,060
Stock Options	\$2.82	6,043,164
RSUs	\$3.15	402,500
Warrants**	\$11.13	10,310,543
Fully Diluted Shares		67,781,267

*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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- 3 NPM-139 (semaglutide implant) is also under development for chronic weight management with the added potential benefit of once-yearly administration.
- 4 Vivani is well-positioned to advance NPM-115 and NPM-119 towards potentially transformational milestones in 2024.