



Nasdaq: VANI

www.vivani.com

Vivani Medical, Inc.

Guaranteed Adherence. Better Outcomes.

May 15, 2023

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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 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 proprietary, NanoPortal™ platform technology enables the design of implants aimed at improving medication non-adherence and tolerability, barriers to patients receiving the full potential benefits of their medicine.

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. Our Phase 2 clinical study of NPM-119 in T2D patients, named LIBERATE-1, is on schedule to start in 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

	Indication	Feasibility	Pre-Clinical	Clinical	Market Size*
Vivani	Human Type II Diabetes and Obesity	NPM-119 exenatide			>\$20B
	Feline Pre-Diabetes & Diabetes	OKV-119** exenatide			>\$500M
	NASH (Non-Alcoholic Steatohepatitis)	NPM-159*** proprietary compound			>\$18B
	Human Obesity	NPM-139*** proprietary compound			>\$19B

* 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



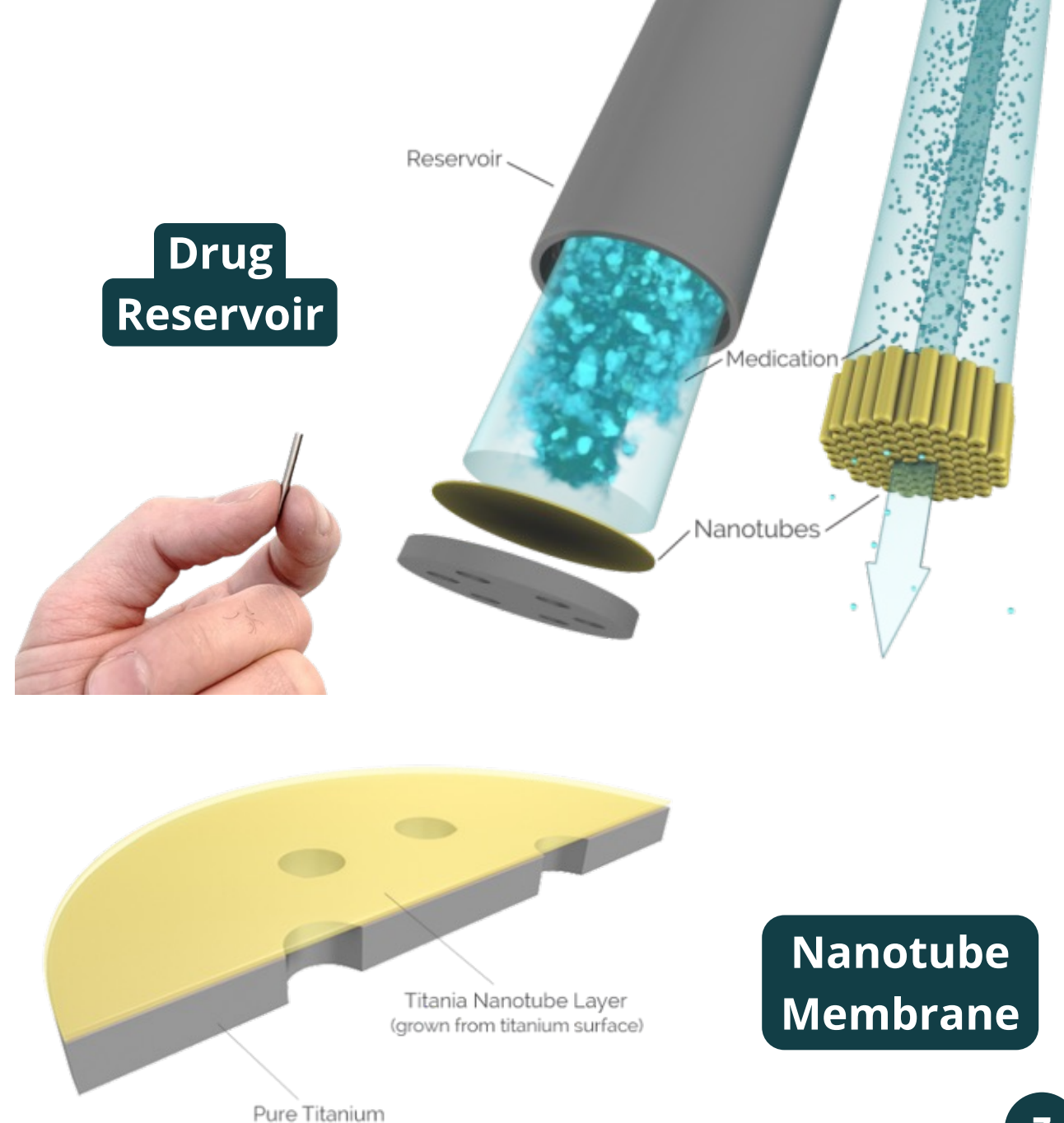
Designed to Assure Adherence



Minimally-fluctuating and tunable delivery profiles



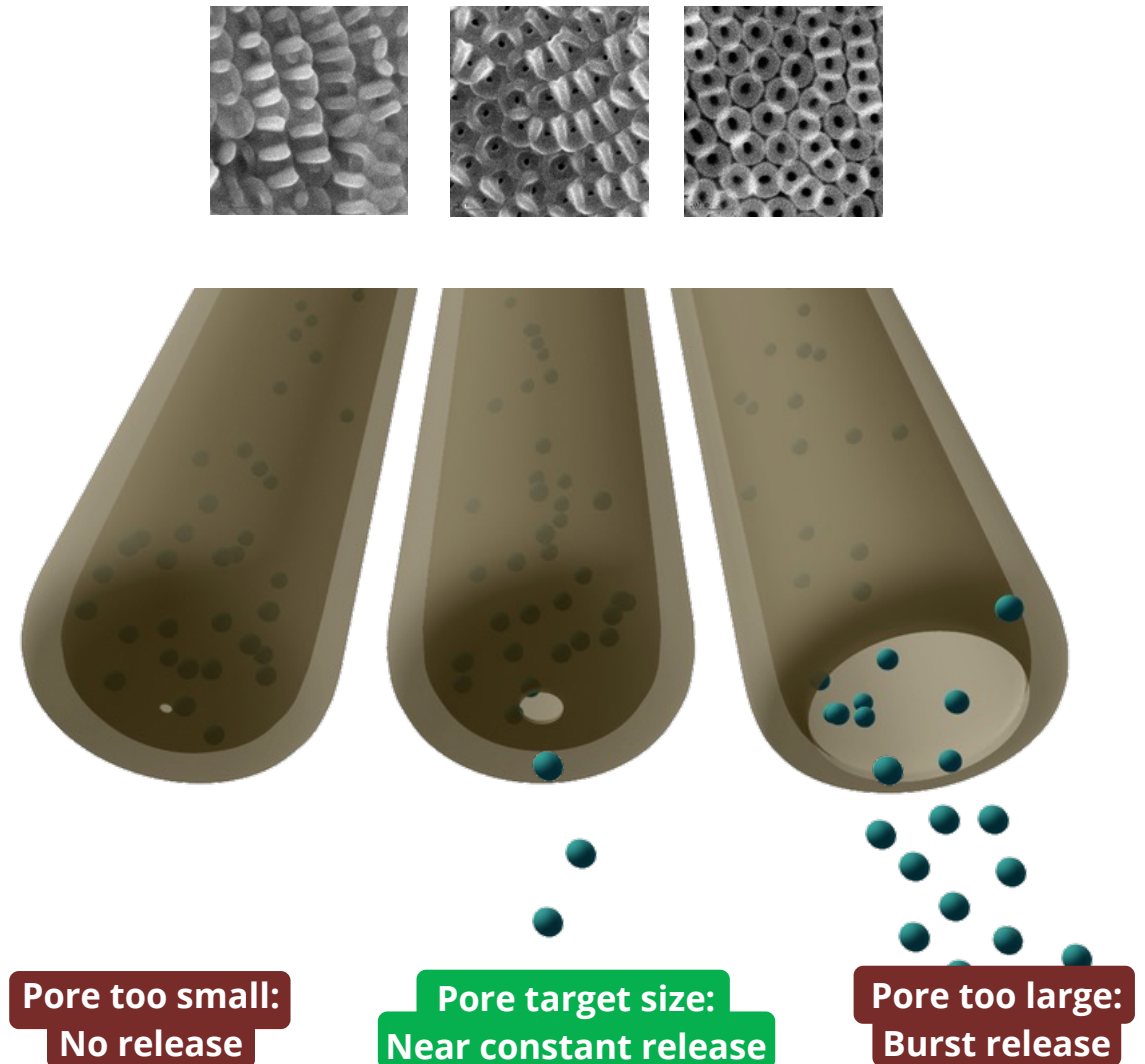
Potential application with many molecular types



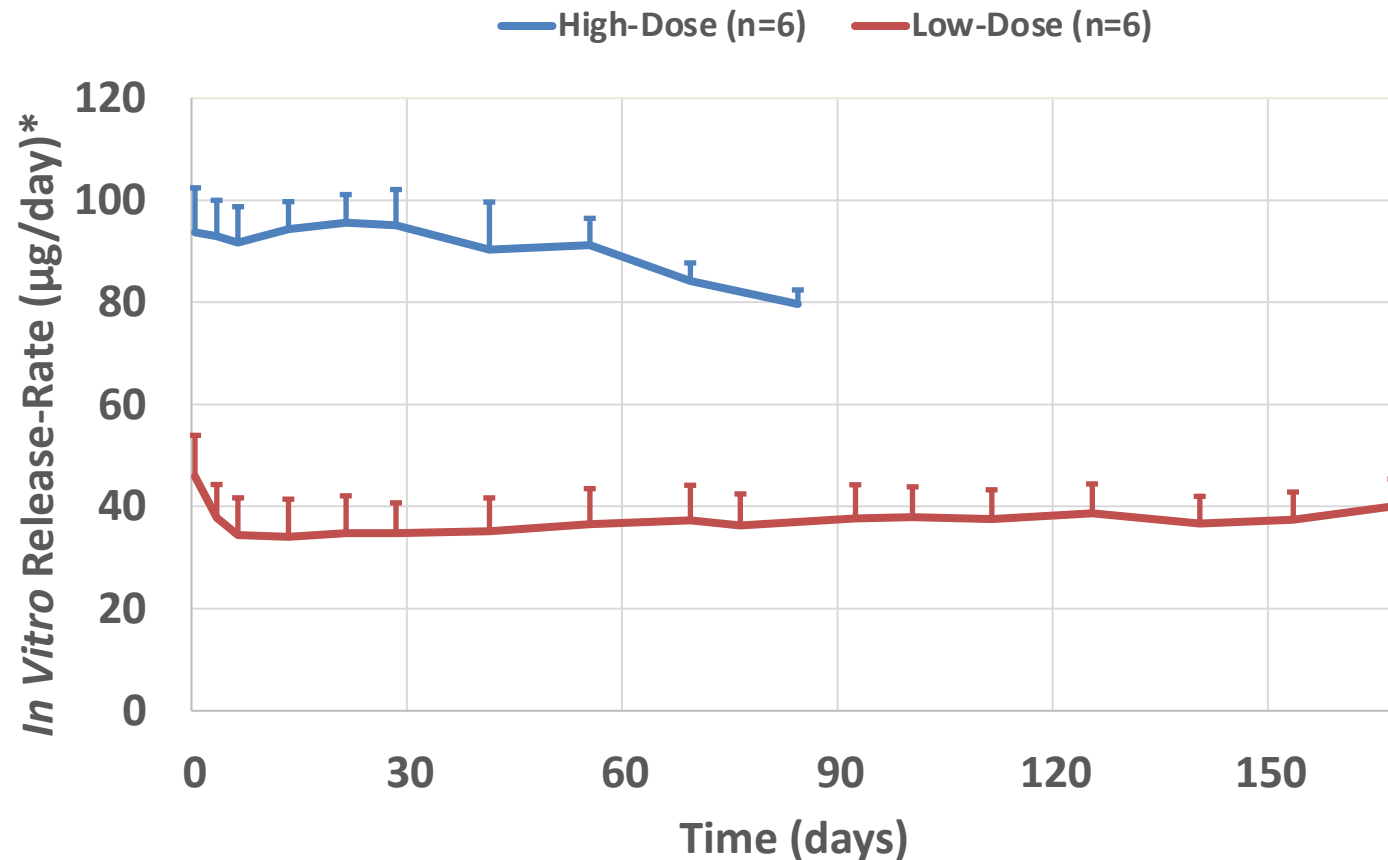
NanoPortal:

How it Works...

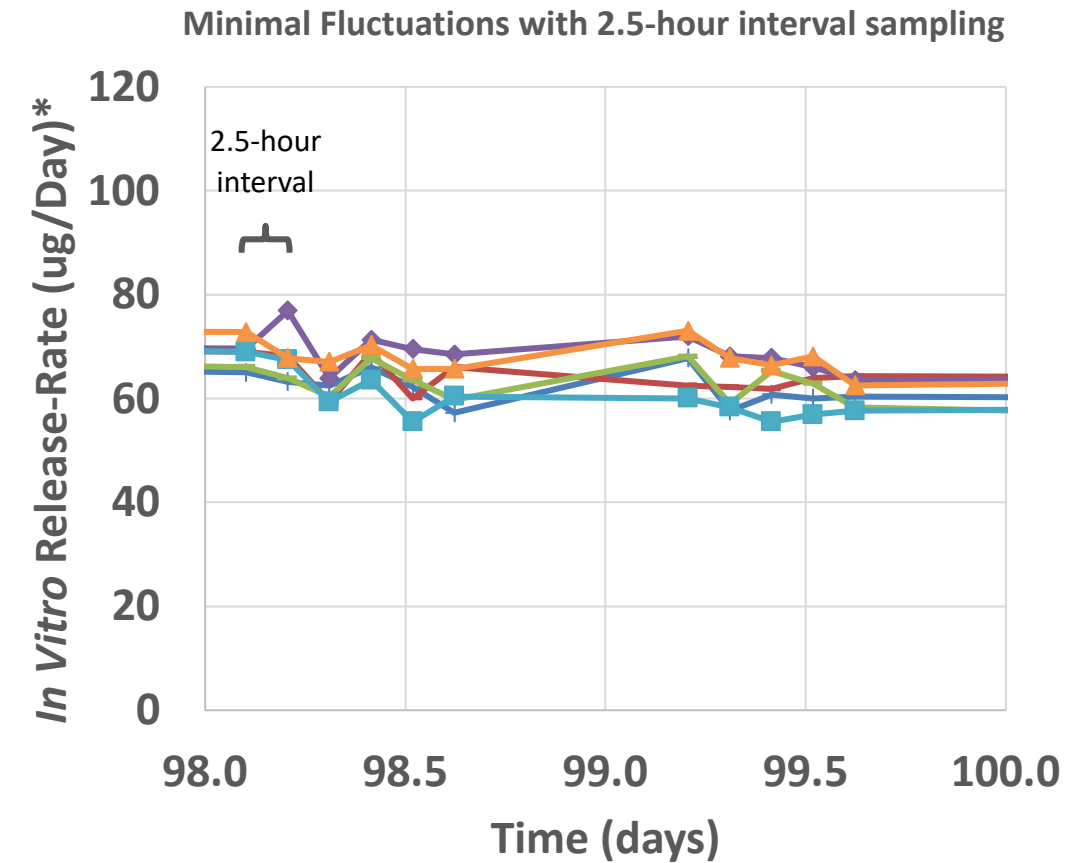
By precisely adjusting nanotubes to molecule size, interactions between drug and nanotube walls can result in desirable release profiles over time, including **near constant release**



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



Minimized Implant Size



Extendable Implant Duration



Tunable Delivery Rate



Tunable Delivery Profile

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

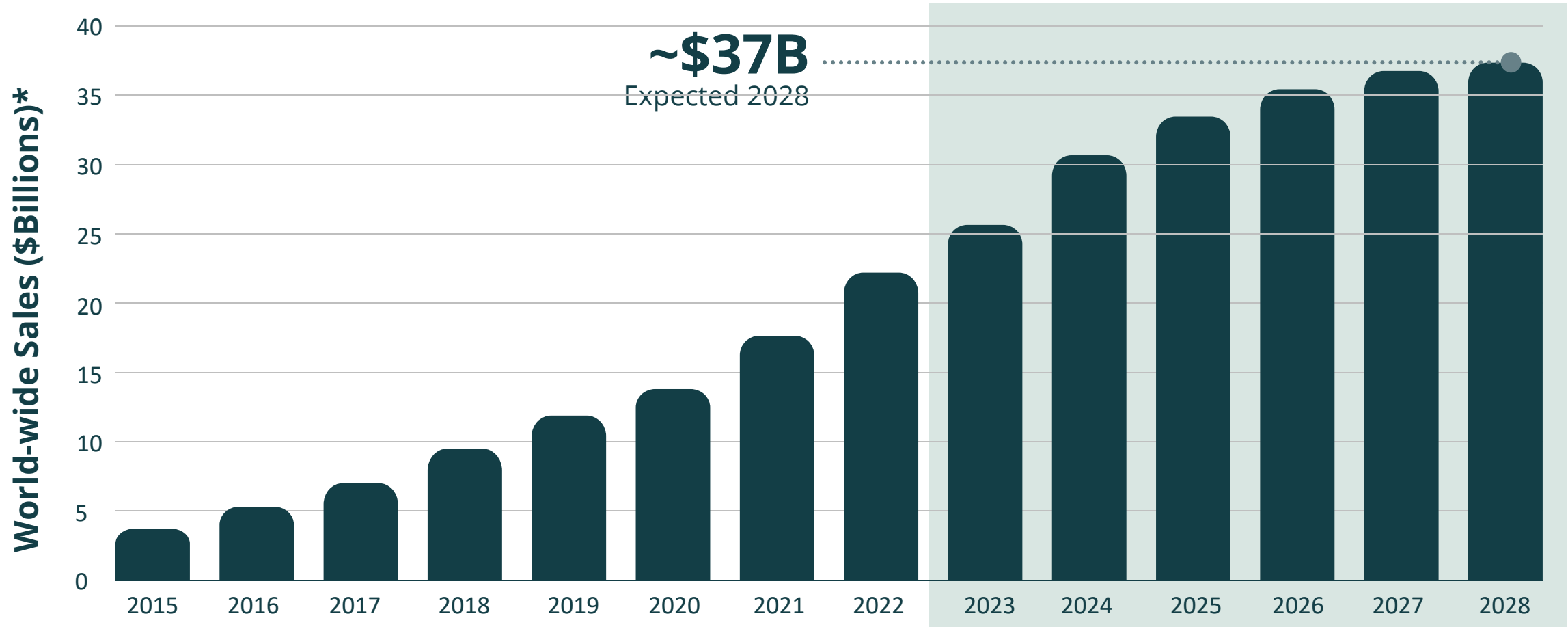
- Non-adherence is the primary reason for low, real-world effectiveness^{1,2}
- Guaranteed adherence will produce significant healthcare cost savings³
- FDA indicated 505(b)(2) streamlined approval pathway may be available
- ~\$54M raised pre-merger from investors including AstraZeneca

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"

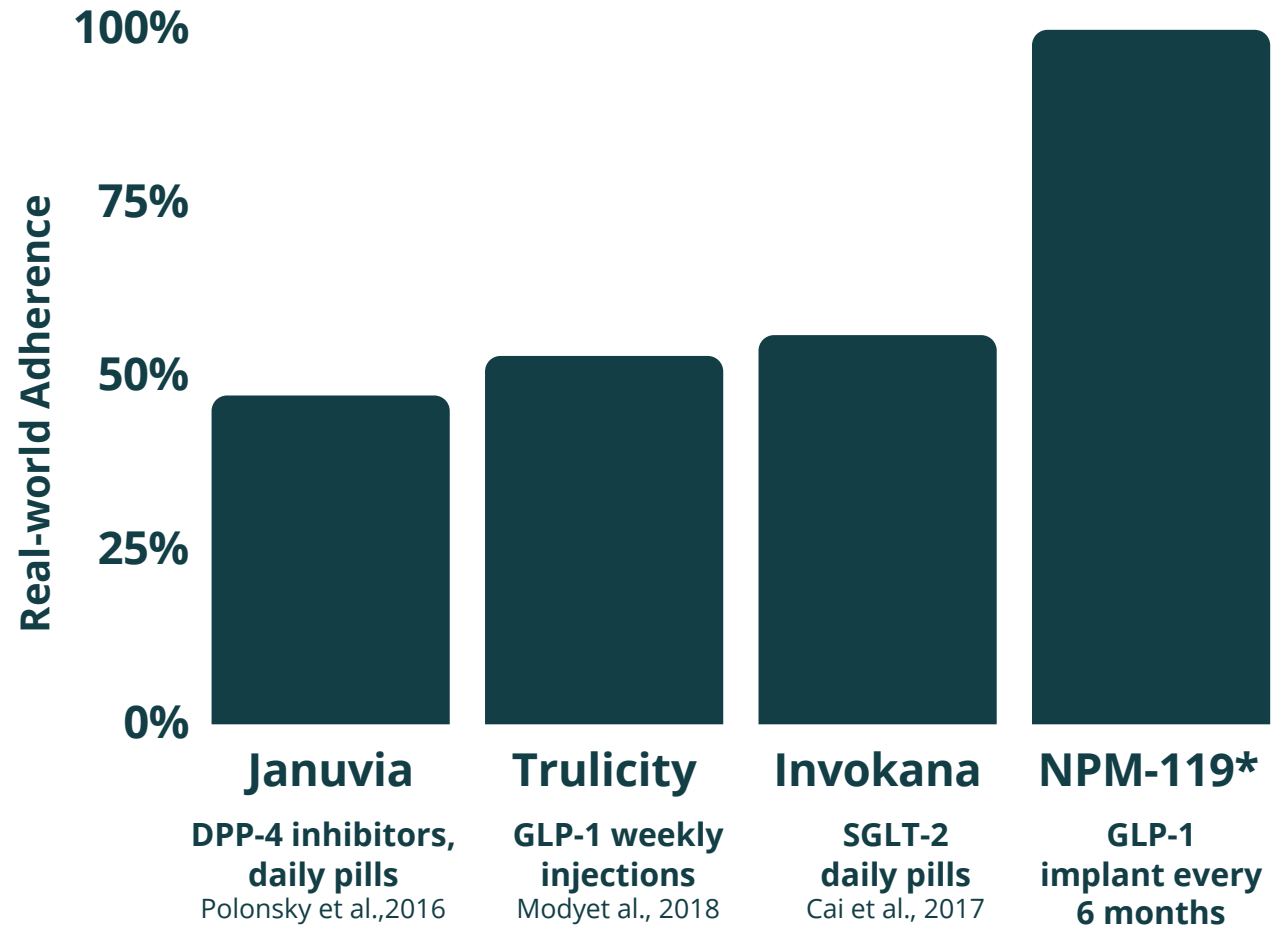
NPM-119 Designed to Enable 100% Adherence through Implant Duration

- 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

Real-World Adherence of Select Drugs



* NPM-119 – under development, not approved in any market

* 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

Drug Substance	Administration	Drug Product
exenatide (GLP-1 Receptor Agonist)	Weekly Injection	BYDUREON®
dulaglutide (GLP-1 Receptor Agonist)	Weekly Injection	
semaglutide (GLP-1 Receptor Agonist)	Weekly Injection Daily Pill	OZEMPIC® semaglutide injection 0.5mg/1mg RYBELSUS® semaglutide tablets
exenatide (GLP-1 Receptor Agonist)	6-Month Implant	NPM-119*

* NPM-119 – under development, not approved in any market

Intarcia's 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* (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 agrees to grant public hearing to Intarcia / Date for Advisory Committee pending

* CRL: Complete Response Letter – issued by FDA to identify NDA deficiencies

NPM-119 well-positioned to avoid Intarcia'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

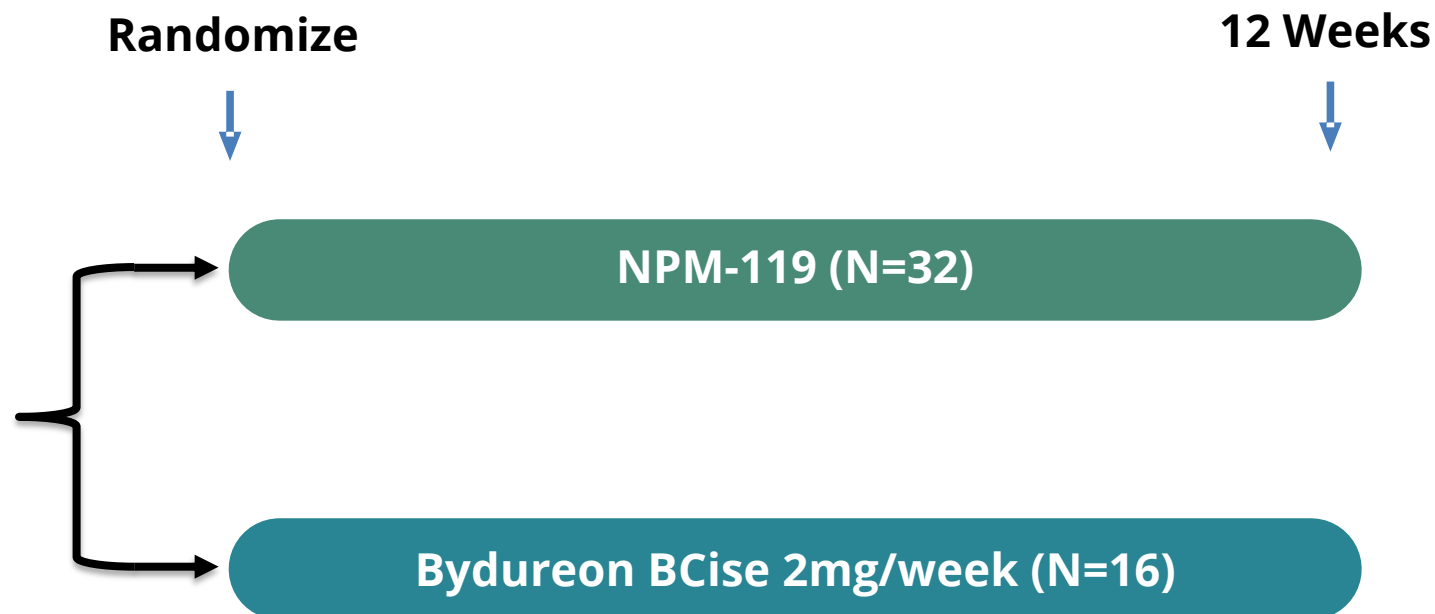
Proposed First in Human Trial: LIBERATE-1

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 $\geq 6.5\%$ 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



NPM-119 Clinical + Regulatory Development

Near-Term Plan

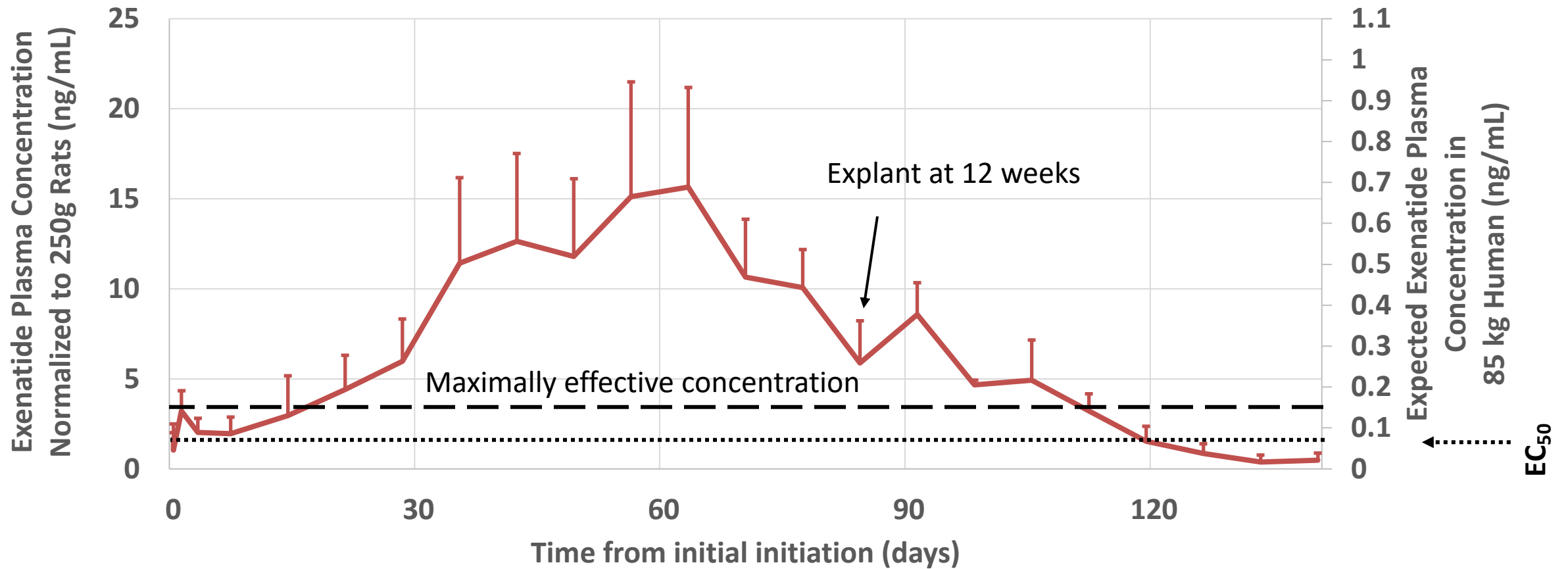
Year(s)	Milestone	Status
2020	FDA Pre-IND Meeting	Completed
Mid-2023	File IND to support Ph 2 (LIBERATE-1) clinical study	On-Track
2024	Deliver LIBERATE-1 top-line results	Projected

We expect to utilize the 505(b)(2) pathway, which permits submissions to rely, in part, on the safety and effectiveness of a previously approved product, which may potentially result in a significantly more expeditious and cost-effective pathway to FDA approval than is typically required for new diabetes therapeutics.

Progress towards IND-enabling activities:

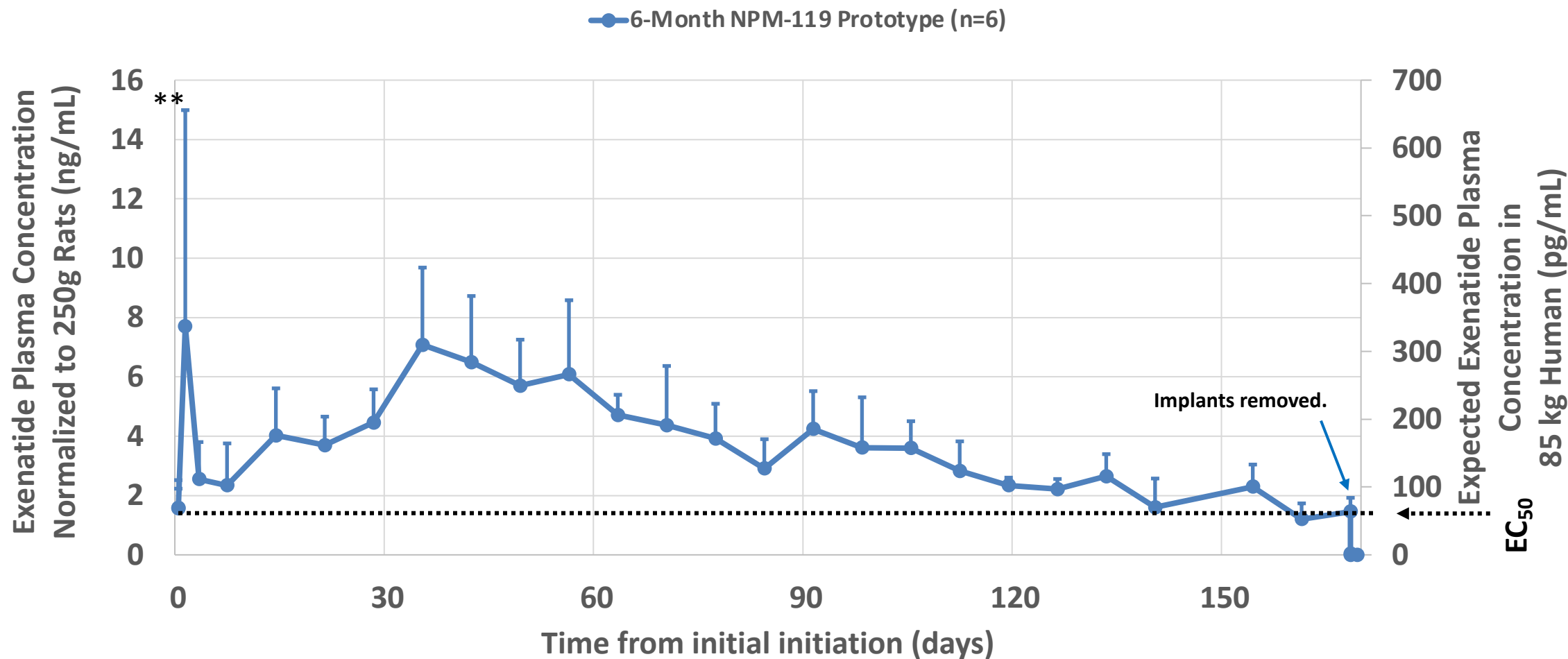
- Development of NPM-119 to be used in LIBERATE-1 is complete
- Recent extensive studies have confirmed excellent biocompatibility of NPM-119's device constituent
- NPM-119 was well tolerated in a preclinical GLP toxicology study
- IND-enabling data is complete
- GMP production of LIBERATE-1 clinical supplies is underway

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.

Q1 2023: P&L Statement

Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development, net of grants	\$ 3,955	\$ 2,679
General and administrative, net of grants	2,646	1,228
Total operating expenses	6,601	3,907
Loss from operations	(6,601)	(3,907)
Other income (expense), net	283	(17)
Net loss	\$ (6,318)	\$ (3,924)
Net loss per common share – basic and diluted	\$ (0.12)	\$ (0.11)
Weighted average common shares outstanding – basic and diluted	50,755	36,806

Vivani Medical, Inc.

Q1 2023: Balance Sheet

Condensed and Consolidated Balance Sheet (unaudited) (in thousands)

	For period ended	
	Mar. 31, 2023	Dec. 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$38,073	\$45,076
Prepaid expenses and other current assets	2,611	2,452
Total current assets	\$40,684	\$47,528
Property and equipment, net	1,111	1,182
Right-of-use assets	1,148	779
Restricted cash	1,366	1,366
Deposits and other assets	271	275
Total assets	\$44,580	\$51,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	\$5,863	\$6,822
Total liabilities	\$6,212	\$6,822
Stockholders' equity:		
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding	\$109,050	\$109,050
Addition paid-in capital and accumulated deficit	(70,682)	(64,742)
Total stockholders' equity	38,368	44,308
Total liabilities and stockholders' equity	\$44,580	\$51,130

Vivani Medical, Inc.

Q1 2023: Cap Table

<i>As of March 31, 2023</i>		
Equity	WAEP*	Number of Shares
Common Stock		50,793,799
Stock Options	\$2.81	6,055,229
RSUs	\$3.15	402,500
Warrants **	\$11.13	10,310,543
Fully Diluted Shares		67,562,071

**Weighted Average Exercise Price*

***Actual warrants total 15, 437,918 including 7,680,938 for Second Sight which when exercised 3 for 1, convert to 2,560,313 common shares*

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