

May 13, 2024



# Vivani Medical Provides Business Update and Reports First Quarter 2024 Financial Results

***Company continues advancing the development of miniature, long-term GLP-1 implants for the treatment of chronic weight management in obese or overweight patients, type 2 diabetes, and other chronic diseases***

***Stable financial position supports operations into the second half of 2025 and potential delivery of key portfolio milestones***

ALAMEDA, Calif.--(BUSINESS WIRE)-- Vivani Medical, Inc. (Nasdaq: [VANI](#)) ("Vivani" or the "Company"), a biopharmaceutical company developing miniaturized, long-term drug implants including its lead asset NPM-115 for chronic weight management in obese or overweight patients with one or more risk factors, today reported financial results for the first quarter ended March 31, 2024, and provided a business update.

Adam Mendelsohn, Ph.D., Vivani's Chief Executive Officer, stated, "Since pivoting to prioritize the development of our GLP-1 implants for obesity and chronic weight management, we have initiated preclinical activities for NPM-115, our high-dose exenatide implant to support clinical investigations. An Investigational New Drug ("IND") application for NPM-115 remains on track for submission before the end of this year. In addition, we remain on track to provide the U.S. Food and Drug Administration ("FDA") with the requested Chemistry, Manufacturing and Controls ("CMC") information related to our NPM-119 IND in the first half of this year."

Dr. Mendelsohn added, "The commercial opportunity for GLP-1 products remains robust with remarkable growth and significant potential for differentiated products including our miniature, subdermal implants with a target frequency of administration of six months or longer. We believe that the largest positive real-world impact in the GLP-1 category will be realized by addressing medication adherence and avoiding the weight regain which occurs upon treatment discontinuation, both of which are directly addressed by our miniature GLP-1 implants in development. As a result, we believe that our pipeline assets continue to hold significant potential opportunity for patients, caregivers, prescribers and payers."

## Recent Business Highlights

In February 2024, Vivani announced positive NPM-115 preclinical weight loss data comparable to semaglutide, the active ingredient in Ozempic® and Wegovy®. In a study of high-fat diet-induced obese mice, NPM-115 generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to weight

loss observed in mice treated with injections of Ozempic in the same study. The Company also disclosed semaglutide as the active pharmaceutical ingredient in NPM-139, a miniature, subdermal GLP-1 implant in development for chronic weight management, with the added potential benefit of once-yearly administration.

In March 2024, Vivani completed a \$15-million registered direct offering of common stock and warrants. Proceeds from the financing will enable acceleration of priority development programs, including NPM-115 for obesity, and fund operations into the second half of 2025.

In March 2024, Vivani also announced the appointment of Daniel Bradbury to its Board of Directors. Under Bradbury's leadership as Chief Executive Officer, Amylin Pharmaceuticals, Inc., with partner Alkermes plc, secured the 2012 approval of Bydureon® (exenatide injection), the world's first once-weekly GLP-1 receptor agonist, a class of drugs that now includes blockbusters Ozempic®, Trulicity® and Wegovy®.

### **Upcoming Anticipated Milestones**

- Vivani anticipates filing the NPM-115 IND application in the second half of 2024 and initiating a first-in-human trial after receiving regulatory clearance to proceed.
- Vivani remains on track to provide the FDA with the requested CMC information associated with the current Clinical Hold on NPM-119 during the first half of 2024.
- Vivani plans to participate in multiple external events, including the TIDES USA conference on Oligonucleotide and Peptide Therapeutics on May 17, 2024 in Boston, MA, where Dr. Mendelsohn will present new NPM-115 data, as well as the Annual BIO International Conference in San Diego, CA on June 3-5, 2024, where Dr. Mendelsohn and Vivani's Chief Business Officer Don Dwyer will meet with potential partners, investors and other industry representatives.

### **First Quarter 2024 Financial Results**

*Cash balance:* As of March 31, 2024, Vivani had cash, cash equivalents and restricted cash totaling \$31.0 million, compared to \$22.0 million as of December 31, 2023. The increase of \$9.0 million is attributed to the net cash provided by issuance of common stock and warrants in connection with securities purchase agreement of \$13.7 million, \$1.0 million provided by a net change in operating assets and liabilities and non-cash items totaling \$0.5 million for depreciation and amortization of property and equipment, stock-based compensation and lease expense, partially offset by a net loss of \$6.0 million and \$0.2 million used for purchase of property and equipment.

*Research and development expense:* Research and development expense during the three months ended March 31, 2024 was \$3.7 million, compared to \$4.0 million during the three months ended March 31, 2023. The decrease of \$0.3 million, or 6%, was primarily attributable to a decrease in costs from the Company's wholly owned subsidiary Cortigent and drug implant development costs, partially offset by increased payroll and personnel-related costs and increased rent due to the lease agreement in Alameda, California and related facilities expense.

*General and administrative expense:* General and administrative expense during the three

months ended March 31, 2024 was \$2.5 million, compared to \$2.6 million during the three months ended March 31, 2023. The decrease of \$0.1 million, or 5%, was attributable to a decrease in costs from Cortigent, partially offset by increased payroll and personnel-related costs, increased rent due to the lease agreement in Alameda, California and professional service expense.

*Other income, net:* Other income, net during the three months ended March 31, 2024 was \$0.2 million, compared to \$0.3 million during the three months ended March 31, 2023. The change was not significant.

*Net Loss:* The net loss during the three months ended March 31, 2024 was \$6.0 million, compared to \$6.3 million during the three months ended March 31, 2023. The decrease in net loss of \$0.3 million was primarily attributable to a decrease in operating expenses of \$0.4 million.

Bydureon® is a registered trademark of the AstraZeneca group of companies.

Ozempic® and Wegovy® are registered trademarks of Novo Nordisk A/S.

Trulicity® is a registered trademark of Eli Lilly and Company.

### **About Vivani Medical, Inc.**

Leveraging its proprietary NanoPortal™ platform, Vivani develops biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence, and potentially to improve medication tolerability. Vivani's lead programs NPM-115 and NPM-119 are miniature, six-month, GLP-1 implants in development for the treatment of chronic weight management in obese or overweight patients and type 2 diabetes, respectively. Both NPM-115 and NPM-119 are exenatide based products with a higher-dose associated with NPM-115 for the treatment of chronic weight management in obese or overweight patients. These NanoPortal implants are designed to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the challenges associated with the daily or weekly administration of orals and injectables. Medication non-adherence occurs when patients do not take their medication as prescribed. This affects an alarming number of patients, approximately 50%, including those taking daily pills. Medication non-adherence, which contributes to more than \$500 billion in annual avoidable healthcare costs and 125,000 potentially preventable deaths annually in the U.S. alone, is a primary and daunting reason why obese or overweight patients, and patients taking type 2 diabetes or other chronic disease medications face significant challenges in achieving positive real-world effectiveness.

### **About Cortigent, Inc.**

Vivani's wholly owned subsidiary, Cortigent, is developing precision neurostimulation systems intended to help patients recover critical body functions. Investigational devices include Orion®, designed to provide artificial vision to people who are profoundly blind, and a new system intended to accelerate the recovery of arm and hand function in patients who are partially paralyzed due to stroke. The company has developed, manufactured, and marketed an implantable visual prosthetic device, Argus II®, that delivered meaningful visual perception to blind individuals. Vivani continues to assess strategic options for advancing

Cortigent's pioneering technology.

## **Forward-Looking Statements**

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the US Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that in this press release, including statements regarding our business, product candidates, including the therapeutic potential thereof and the planned development therefor, technology and strategy. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, risks related to the development and commercialization of our product candidates, including NPM-115 and NPM-119; delays and changes in applicable laws, regulations and guidelines including potential delays in submitting required regulatory applications to the FDA; risks related to the initiation, enrollment and conduct of our planned clinical trials and the results therefrom; our history of losses and our ability to achieve or sustain profitability in the future; and the impact of COVID-19 on our business. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties can be found in the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2023 filed with the U.S. Securities Exchange Commission ("SEC") on March 26, 2024, and any subsequent filings filed with the SEC. Any forward-looking statement made by us in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of added information, future developments or otherwise, except as required by law.

**VIVANI MEDICAL, INC.  
AND SUBSIDIARIES**

**Condensed Consolidated Balance Sheets (unaudited)**  
(in thousands, except per share data)

	<b>March 31, 2024</b>	<b>December 31, 2023</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 29,648	\$ 20,654
Prepaid expenses and other current assets	1,854	2,408
Total current assets	31,502	23,062
Property and equipment, net	1,689	1,729
Right-of-use assets	19,212	19,616
Restricted cash	1,338	1,338
Other assets	47	52
Total assets	<u>\$ 53,788</u>	<u>\$ 45,797</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 570	\$ 542
Accrued expenses	1,953	1,727
Litigation accrual	1,675	1,675
Accrued compensation expense	506	396
Current operating lease liabilities	1,434	1,383
Total current liabilities	6,138	5,723
Long-term operating lease liabilities	18,940	19,313
Total liabilities	25,078	25,036
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$0.0001 per share; 10,000 shares authorized; none outstanding	-	-
Common stock, par value \$0.0001 per share; 300,000 shares authorized; shares issued and outstanding: 54,978 and 51,031 at March 31, 2024 and December 31, 2023, respectively	5	5
Additional paid-in capital	133,094	119,054
Accumulated other comprehensive income	88	140
Accumulated deficit	(104,477)	(98,438)
Total stockholders' equity	28,710	20,761
Total liabilities and stockholders' equity	<u>\$ 53,788</u>	<u>\$ 45,797</u>

**VIVANI MEDICAL, INC.  
AND SUBSIDIARIES**

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

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Operating expenses:		
Research and development, net of grants	\$ 3,726	\$ 3,955
General and administrative, net of grants	2,501	2,646
Total operating expenses	6,227	6,601
Loss from operations	(6,227)	(6,601)
Other income, net	188	283
Net loss	\$ (6,039)	\$ (6,318)
Net loss per common share - basic and diluted	\$ (0.12)	\$ (0.12)
Weighted average common shares outstanding - basic and diluted	52,202	50,755

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