

March 26, 2024



# Vivani Medical Provides Business Update and Reports Fourth Quarter and Full Year 2023 Financial Results

***Strategic shift prioritizes the development of GLP-1 implants for the treatment of obesity and chronic weight management***

***Positive NPM-115 (exenatide implant) preclinical weight loss data comparable to semaglutide, active ingredient in Ozempic®/Wegovy®***

***\$15 million financing round enables acceleration of priority development programs and secures operations into the second half of 2025***

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 fourth quarter and full year ended December 31, 2023, and provided a business update.

Adam Mendelsohn, Ph.D., Vivani's Chief Executive Officer, stated, "2023 was another remarkable year for Vivani as we shifted our strategic focus to our obesity portfolio and announced that our lead program NPM-115 – a six-month GLP-1 implant for obesity – generated preclinical weight loss data comparable to semaglutide, the active ingredient in Ozempic® and Wegovy®. We 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, we raised funding to support operations into the second half of 2025. Additionally, we moved into a dedicated facility in Alameda, California, capable of supporting the manufacturing of large-scale clinical trial materials and, ultimately, commercial supply."

Dr. Mendelsohn added, "We are on track to submit a new Investigational New Drug Application for NPM-115, our high-dose exenatide implant for chronic weight management in obese and overweight patients with one or more risk factors, later this year. We also remain on track to provide the U.S. Food and Drug Administration with the requested NPM-119 Chemistry, Manufacturing and Controls information in the first half of this year, with the goal of obtaining an Investigational New Drug Application clearance of NPM-119 to initiate clinical development. The considerable work we have done to prepare NPM-119 for clinical development will be leveraged as we move toward a first-in-human clinical study for NPM-115, which aligns with our new strategic priority."

## Recent Business Highlights

In March 2024, Vivani announced the pricing of 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 provides funding of 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 CEO, Amylin Pharmaceuticals, with partner Alkermes, 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.

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 in 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. Vivani announced the addition of NPM-115 to its portfolio in November 2023. Adding to Vivani's emerging obesity portfolio, 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.

Moving forward, Vivani will focus on developing NPM-115 and its emerging pipeline of innovative miniature, long-term drug implants to treat patients with chronic diseases and high unmet medical need. Today, the Company has grown to nearly 40 full-time employees and its current headquarters and operations are located at 1350 S. Loop Road, Alameda, California.

### **Upcoming Anticipated Milestones**

- Vivani anticipates filing the NPM-115 Investigational New Drug Application in the second half of 2024 and initiating a first-in-human trial after receiving regulatory clearance to proceed.
- The Company anticipates filing a Complete Response to the current Clinical Hold on NPM-119 during the first half of 2024.
- Vivani is seeking U.S. Securities and Exchange Commission (the "SEC") approval to proceed with an initial public offering for wholly owned subsidiary Cortigent, Inc. Assuming successful financing is secured, the Company plans to continue advancing Cortigent's pioneering precision neurostimulation technology for providing meaningful, visual perception in blind people and motor function in impaired stroke patients.

### **Fourth Quarter 2023 Financial Results**

*Cash Balance:* As of December 31, 2023, Vivani had cash, cash equivalents and restricted cash totaling \$22.0 million, compared to \$46.4 million as of December 31, 2022. The decrease of \$24.5 million is primarily attributed to a net loss of \$25.7 million, \$1.3 million used from a net change in operating assets and liabilities and \$0.9 million related to purchase of equipment. The decrease was partially offset by non-cash items totaling \$3.2 million for depreciation and amortization of property and equipment, stock-based compensation, loss on disposal of fixed assets and lease expense.

*Research and development expenses:* Research and development expenses during the fourth quarter of 2023 were \$4.7 million, compared to \$4.4 million during the fourth quarter of 2022. The increase of \$0.3 million, or 6%, was primarily attributable to increased payroll and personnel-related costs, increased rent and related facilities expense due to the lease agreement in Alameda, California, partially offset by lower spending on drug implants development costs.

*General and administrative expenses:* General and administrative expenses during the fourth quarter of 2023 were \$1.5 million, compared to \$3.4 million during the fourth quarter of 2022. The decrease of \$1.9 million, or 55%, was primarily attributable to a provision for a legal claim of \$1.7 million recorded in the fourth quarter of 2022.

*Other income (expense):* Other income (expense), net during the fourth quarter of 2023 was \$0.2 million, compared to \$0.5 million during the fourth quarter of 2022. The decrease of \$0.3 million, or 62%, was primarily attributed to a decrease in interest income on cash investments.

*Net Loss:* The net loss during the fourth quarter of 2023 was \$6.0 million, compared to \$7.3 million during the fourth quarter of 2022. The decrease in net loss of \$1.3 million was primarily attributable to a decrease in operating expenses of \$1.6 million, partially offset by a decrease in interest income on cash investments.

## **Full Year 2023 Financial Results**

*Research and development expenses:* Research and development expenses during the year ended December 31, 2023 was \$17.0 million, compared to \$14.2 million during the year ended December 31, 2022. The increase of \$2.8 million, or 20%, was primarily attributable to increased payroll and personnel-related costs, increased rent due to the lease agreement in Alameda, California and related facilities expense and the inclusion of Cortigent (former legacy company Second Sight), since the merger acquisition date of August 30, 2022, partially offset by drug implant development costs.

*General and administrative expenses:* General and administrative expenses during the year ended December 31, 2023 was \$10.0 million, compared to \$7.1 million during the year ended December 31, 2022. The increase of \$2.9 million, or 41%, was primarily attributable to increased payroll and personnel-related expenses, increased rent and related facilities expense due to the lease agreement in Alameda, California, insurance costs, professional service expense and the inclusion of Cortigent, since the merger acquisition date of August 30, 2022, partially offset by a provision for a legal claim of \$1.7 million recorded in 2022.

*Other income (expense), net:* Other income (expense), net during the year ended December 31, 2023 was \$1.3 million, compared to \$7.4 million during the year ended December 31, 2022. Other income consisted of interest income of \$1.5 million during the year ended December 31, 2023. Other income during the year ended December 31, 2022 included \$6.9 million related to a gain on bargain purchase from the acquisition of Second Sight and interest income.

*Net Loss:* The net loss during the year ended December 31, 2023 was \$25.7 million, compared to \$13.9 million during the year ended December 31, 2022. The increase in net loss of \$11.8 million was primarily attributable to an increase in operating expenses of \$5.7

million and the prior year gain on the bargain purchase from the acquisition of Second Sight of \$6.9 million, partially offset by increased interest income due to higher average investments and rate increases on cash investments.

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

Leveraging its proprietary NanoPortal™ platform, Vivani Medical 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**

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 U.S. Food and Drug Administration (“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 Quarterly Report on Form 10-Q, 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>December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 20,654	\$ 45,076
Prepaid expenses and other current assets	2,408	2,452
Total current assets	23,062	47,528
Property and equipment, net	1,729	1,182
Right-of-use assets	19,616	779
Restricted cash	1,338	1,366
Deposits and other assets	52	275
Total assets	<u>\$ 45,797</u>	<u>\$ 51,130</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 542	\$ 1,177
Accrued expenses	1,727	2,358
Litigation accrual	1,675	1,675
Accrued compensation expense	396	657
Current operating lease liabilities	1,383	955
Total current liabilities	5,723	6,822
Long-term operating lease liabilities	19,313	-
Total liabilities	<u>25,036</u>	<u>6,822</u>
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: 51,031 and 50,736 as of December 31, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	119,054	117,054
Accumulated other comprehensive gain	140	35
Accumulated deficit	(98,438)	(72,786)
Total stockholders' equity	<u>20,761</u>	<u>44,308</u>
Total liabilities and stockholders' equity	<u><u>\$ 45,797</u></u>	<u><u>\$ 51,130</u></u>

**VIVANI MEDICAL, INC.  
AND SUBSIDIARIES**

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

	<b>Three Months Ended December 31,</b>		<b>Twelve Months Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Operating expenses:				
Research and development, net of grants	\$ 4,708	\$ 4,427	\$ 16,968	\$ 14,169
General and administrative, net of grants	1,509	3,363	9,997	7,072
Total operating expenses	6,217	7,790	26,965	21,241
Loss from operations	(6,217)	(7,790)	(26,965)	(21,241)
Other income (expense), net	191	506	1,313	7,352
Net loss	<u>\$ (6,026)</u>	<u>\$ (7,284)</u>	<u>\$ (25,652)</u>	<u>\$ (13,889)</u>
Net loss per common share - basic and diluted	\$ (0.12)	\$ (0.14)	\$ (0.50)	\$ (0.36)
Weighted average shares outstanding - basic and diluted	<u>51,025</u>	<u>50,736</u>	<u>50,853</u>	<u>38,241</u>

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Source: Vivani Medical, Inc.