August 13, 2024

Vivani Medical Provides Business Update and Reports Second Quarter 2024 Financial Results

Initiation of the NPM-115 clinical program expected in the fourth quarter of 2024 with a first-in-human study evaluating a miniature, subdermal GLP-1 (exenatide) implant in obese or overweight patients

FDA provided clearance of the Investigational New Drug Application for NPM-119, providing further confidence to advance the Company's emerging portfolio of GLP-1 implants into clinical phase development

Solid 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-acting drug implants, today reported financial results for the second quarter ended June 30, 2024, and provided a business update.

Vivani's Chief Executive Officer Adam Mendelsohn, Ph.D., stated, "During the second quarter we achieved significant progress toward advancing the development of our proprietary, GLP-1 implants for obesity and chronic weight management, and anticipate the initiation of our first-in-human clinical study in the fourth quarter of this year. After successfully addressing the FDA's requests for additional Chemistry, Manufacturing and Controls information and securing clearance on our NPM-119 Investigational New Drug Application in the first half of this year, Vivani is now on the cusp of transitioning to a clinical-stage development phase biotechnology company, now in position to initiate clinical testing in the fourth quarter of this year."

Dr. Mendelsohn added, "Our highly differentiated portfolio of miniature, ultra long-acting GLP-1 implants have the potential to directly address medication non-adherence and tolerability, two significant barriers to achieving optimal therapy for chronic weight management and other chronic diseases. An alarmingly high proportion of chronic disease patients, approximately 50%, do not take their medicine as prescribed in the real world, a statistic which holds for both daily orals as well as weekly injectables. In addition, a recent study has shown that 64% of patients taking the popular GLP-1 therapy Wegovy® (semaglutide for weight management) discontinue therapy within the first year, a number which increases to 76% by year two. Importantly, GLP-1 therapy discontinuation is associated with a quick reversal of the GLP-1 health benefits for most patients. Vivani's pipeline offers the potential to significantly improve the adherence and persistence

challenges these patients currently face."

Recent Business Highlights

In May 2024, Vivani and development partner Okava Pharmaceuticals Inc. announced publication of positive weight loss data supporting the potential veterinary use of OKV-119, a miniature, long-term GLP-1 implant under development for the treatment of pre-diabetes, diabetes and obesity in companion cats. Data published in *BMC Veterinary Research* provided further evidence that Vivani's NanoPortal™ implant technology holds promise in reducing obesity in cats where an estimated 40% of the domestic cat population needs help managing their weight.

In June 2024, the Company announced that the U.S. Food and Drug Administration ("FDA") cleared the Investigational New Drug Application ("IND") for NPM-119, a miniature, six-month, subdermal GLP-1 implant designed to address medication non-adherence and potentially improve tolerability in patients with type 2 diabetes. The proposed first-in-human clinical study was designed to evaluate the safety, tolerability and pharmacokinetic profile of the exenatide implant versus marketed exenatide injectable, Bydureon BCise®.

In July 2024, Vivani provided an update on the clinical development plans for the miniature, long-acting GLP-1 obesity implant program for NPM-115. In support of the recent strategic shift to prioritize the development of its obesity and chronic weight management portfolio, the Company announced revised plans to evaluate its GLP-1 implant as part of the NPM-115 program in patients who are obese or overweight in the company's first-in-human study, LIBERATE-1. This study will enroll patients who will be titrated on weekly semaglutide (Wegovy®) for eight weeks before subsequently being randomized to receive a single exenatide implant, weekly exenatide injections (Bydureon BCise) or weekly semaglutide injections for a nine-week treatment duration. The Company expects the study to be initiated in the fourth quarter of 2024 in Australia, pending regulatory approval, with data from the study anticipated in 2025.

Upcoming Anticipated Milestones

- Vivani anticipates receiving approval from a Human Research Ethics Committee in Australia to support initiation of the Company's first-in-human study, which supports the NPM-115 obesity implant program, during the fourth quarter of 2024. Study results are expected in 2025.

- Vivani plans to participate in multiple industry and investor conferences, including the H.C. Wainwright conference in New York, NY, taking place September 9-12, 2024. The Company will also participate in Maxim's Virtual Healthcare Summit, October 15-17, 2024. Dr. Mendelsohn plans to provide the Company's slide presentations at both conferences.

Second Quarter 2024 Financial Results

Cash balance: As of June 30, 2024, Vivani had cash, cash equivalents and restricted cash totaling $26.3 million, compared to $31.0 million as of March 31, 2024. The decrease of $4.7 million is attributed to a net loss of $5.4 million, partially offset by $0.6 million in non-cash items for depreciation and amortization of property and equipment, stock-based

compensation and lease expense, and a net cash of $0.1 million provided by financing activities.

Research and development expense: Research and development expense during the three months ended June 30, 2024 was $3.5 million, compared to $3.9 million during the three months ended June 30, 2023. The decrease of $0.4 million, or 9%, was primarily attributable to staffing reduction and reduced use of outside services.

General and administrative expense: General and administrative expense during the three months ended June 30, 2024 was $2.2 million, compared to $3.1 million during the three months ended June 30, 2023. The decrease of $1.0 million, or 31%, was attributable to staffing reduction along with reduced outside legal and other professional services.

Other income, net: Other income, net during the three months ended June 30, 2024 was $0.3 million, compared to $0.5 million during the three months ended June 30, 2023. The change was not significant.

Net Loss: The net loss during the three months ended June 30, 2024 was $5.3 million, compared to $6.5 million during the three months ended June 30, 2023. The decrease in net loss of $1.2 million was primarily attributable to a decrease in operating expenses of $1.3 million.

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 tolerance to their medication. Vivani's lead program, NPM-115, is a miniature, six-month, subdermal, GLP-1 (exenatide) implant under development for the treatment of chronic weight management in obese or overweight patients. Vivani's emerging pipeline also includes NPM-139 (semaglutide implant) which is also under development for chronic weight management in obese and overweight patients. NPM-139 has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's six-month, subdermal exenatide implant under development for the treatment of type 2 diabetes. Both NPM-115 and NPM-119 are exenatide based products with a higher-dose associated with NPM-115 for 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 obese or overweight patients, and patients taking type 2 diabetes or other chronic disease treatments face significant challenges in achieving positive real-world effectiveness. While the current GLP-1 landscape includes over 100 new molecular entities under clinical stage development, Vivani remains confident that its highly differentiated portfolio of miniature long-acting GLP-1 implants have the potential to provide

an attractive therapeutic option for patients, prescribers and payers.

About Cortigent, Inc.

Vivani's wholly owned subsidiary, Cortigent, Inc. ("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. Cortigent 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 Vivani's business, products in development, including the therapeutic potential thereof, the planned development therefor, the initiation of the LIBERATE-1 trial and reporting of trial results, Vivani's emerging development plans for NPM-115, NPM-139, or Vivani's plans with respect to Cortigent and its proposed initial public offering, technology, strategy, cash position and financial runway. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on Vivani's 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 Vivani's 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 products, including NPM-115 and NPM-119; delays and changes in the development of Vivani's products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct our development activities, including our ability to commence clinical development of NPM-119; risks related to the initiation, enrollment and conduct of Vivani's planned clinical trials and the results therefrom; our history of losses and Vivani's ability to access additional capital or otherwise fund our business; market conditions and the ability of Cortigent to complete its initial public offering. 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 filed with the U.S. Securities and Exchange Commission filed on March 26, 2024, as updated by The Company's subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by Vivani 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)

	June 30, 2024	December 31, 2023
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
Other assets	38	52
Total assets	$ 48,224	$ 45,797
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 645	$ 542
Accrued expenses	1,660	1,727
Litigation accrual	1,675	1,675
Accrued compensation expense	384	396
Current operating lease liabilities	1,420	1,383
Total current liabilities	5,784	5,723
Long-term operating lease liabilities	18,616	19,313
Total liabilities	24,400	25,036
Commitments and contingencies (Note 11)		
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: **55,197** and **51,031** at June 30, 2024 and December 31, 2023, respectively	6	5
Additional paid-in capital	133,588	119,054
Accumulated other comprehensive income	63	140
Accumulated deficit	(109,833)	(98,438)
Total stockholders' equity	23,824	20,761
Total liabilities and stockholders' equity	$ 48,224	$ 45,797

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development, net of grants	$ 3,513	$ 3,864	$ 7,239	$ 7,819
General and administrative, net of grants	2,168	3,139	4,669	5,785
Total operating expenses	5,681	7,003	11,908	13,604
Loss from operations	(5,681)	(7,003)	(11,908)	(13,604)
Other income, net	325	477	513	760
Net loss	$ (5,356)	$ (6,526)	$ (11,395)	$ (12,844)
Net loss per common share - basic and diluted	$ (**0.10**)	$ (**0.13**)	$ (**0.21**)	$ (**0.25**)
Weighted average common shares outstanding - basic and diluted	**55,021**	**50,795**	**53,612**	**50,748**

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Company Contact:
Donald Dwyer
Chief Business Officer
info@vivani.com
(415) 506-8462

Investor Relations Contact:
Jami Taylor
Investor Relations Advisor
investors@vivani.com
(415) 506-8462

Media Contact:
Sean Leous
ICR Westwicke
Sean.Leous@westwicke.com
(646) 866-4012

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