November 13, 2024

Vivani Medical Provides Business Update Including $5M Equity Financing and Reports Third Quarter 2024 Financial Results

Regulatory approval to initiate first-in-human study with a miniature, ultra long-acting GLP-1 (exenatide) implant in obese or overweight individuals in Australia

Miniature, ultra long-acting GLP-1 implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing

Announces $5M equity financing which secures solid financial position into late 2025, supporting projected completion of first-in-human study and data read-out

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 third quarter ended September 30, 2024, and provided a business update.

Vivani's Chief Executive Officer Adam Mendelsohn, Ph.D., stated, "We made significant progress advancing our proprietary GLP-1 implants for obesity and chronic weight management in the third quarter, and we anticipate the initiation of our first-in-human clinical study, named LIBERATE-1, in the fourth quarter of this year. After choosing to conduct our initial first-in-human study in Australia, in part to take advantage of potentially significant rebates from the Australian government, we were excited to receive the regulatory approvals to initiate LIBERATE-1, as a key element of our NPM-115 clinical program in overweight and obese individuals. Today's $5 million common stock financing announcement puts us in an excellent position to complete LIBERATE-1 and continue development of our pipeline programs in 2025."

Dr. Mendelsohn added, "Our NanoPortal drug delivery technology has the potential to directly address medication non-adherence which is responsible for approximately 125,000 avoidable deaths each year in the US alone, more than caused by breast, colorectal and liver cancer combined. In addition, approximately 50% of patients with chronic diseases, including patients with obesity and type 2 diabetes, do not take their medicine as prescribed in the real world, a statistic which holds for both daily orals as well as weekly injectables. GLP-1 drugs have already improved the health of millions of people with obesity and type 2 diabetes, but the future potential impact of these medicines to improve global health across a variety of new indications is even more remarkable. At Vivani, we are addressing the

tremendous opportunity to revolutionize the treatment of chronic diseases, including obesity, with our emerging pipeline of miniature, ultra long-acting drug implants specifically designed to ensure medication adherence with twice-yearly, and potentially once-yearly, administration that will allow patients to achieve the full potential benefits of their medicine."

Recent Business Highlights

In July 2024, the Company announced that it expects to initiate the first clinical study in the NPM-115 program in the fourth quarter of 2024 in Australia, pending regulatory clearance in that country. The NPM-115 clinical program will evaluate the investigational 6-month GLP-1 implant for chronic weight management in patients who are either obese or overweight with a related comorbidity.

In September 2024, the Company announced that the Bellberry Human Research Ethics Committee approved, and the Therapeutic Goods Administration in Australia formally acknowledged a first-in-human clinical trial of the Company's miniature, subdermal GLP-1 (exenatide) implant in obese and overweight subjects.

Also in September 2024, the Company reported that its exenatide implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing. The Company previously announced sham-implant adjusted preclinical weight loss of 20%, which is comparable to the weight loss produced from the semaglutide (active ingredient in Ozempic®/Wegovy®) injection control arm in the same study.

On November 8, 2024, the Company entered into a private sale transaction with one of its independent directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share. The gross proceeds from this private sale transaction were $5.0 million which secures Vivani's financial position into late 2025 and supports projected completion of the first-in-human study and data read-out.

Upcoming Anticipated Milestones

- Vivani plans to initiate LIBERATE-1, a Phase 1, first-in-human study of a miniature, ultra long-acting GLP-1 (exenatide) implant to investigate the safety, tolerability and full pharmacokinetic profile in obese or overweight subjects. The trial will enroll participants who will be titrated on weekly semaglutide injections for 8 weeks (0.25 mg/week for 4 weeks followed by 0.5 mg/week for 4 weeks) before being randomized to receive a single administration of Vivani's exenatide implant (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. Changes in weight will be measured. Data is projected to be available in 2025.
- Vivani will present at the Innovation in Obesity Therapeutics Summit – West Coast on December 10-12, 2024, in San Diego, CA.

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

Third Quarter 2024 Financial Results

Cash balance: As of September 30, 2024, Vivani had cash, cash equivalents and restricted cash totaling $21.0 million, compared to $26.3 million as of June 30, 2024. The decrease of $5.3 million is attributed to a net loss of $6.0 million, a decrease of $0.3 million changes in operating assets and liabilities, 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 $0.4 million provided by financing activities.

Research and development expense: Research and development expense during the three months ended September 30, 2024 was $4.2 million, compared to $4.4 million during the three months ended September 30, 2023. The decrease of $0.2 million, or 5%, was primarily attributable to staffing reduction in Vivani's neurostimulation business and reduced use of outside services, partially offset by the increase in Alameda site facility expenses.

General and administrative expense: General and administrative expense during the three months ended September 30, 2024 was $2.1 million, compared to $2.7 million during the three months ended September 30, 2023. The decrease of $0.6 million, or 22%, was attributable to staffing reduction in Vivani's neurostimulation business along with reduced outside legal and other professional services.

Other income, net: Other income, net during the three months ended September 30, 2024 was $0.3 million, compared to $0.4 million during the three months ended September 30, 2023. The change was not significant.

Net Loss: The net loss during the three months ended September 30, 2024 was $6.0 million, compared to $6.8 million during the three months ended September 30, 2023. The decrease in net loss of $0.8 million was primarily attributable to a decrease in operating expenses of $0.8 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 patient tolerance to their medication. Vivani's lead program, NPM-115, utilizes a miniature, six-month, subdermal, GLP-1 (exenatide) implant under development for chronic weight management in obese or overweight individuals. Vivani's emerging pipeline also includes the NPM-139 (semaglutide implant) which is also under development for chronic weight management in obese and overweight individuals. The semaglutide implant has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's type 2 diabetes development program utilizing a six-month, subdermal exenatide implant. Both the NPM-115 and NPM-119 programs utilize exenatide based products with a higher-dose associated with the NPM-115 program 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 50 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 Vivani's 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 Vivani's development activities, including Vivani's 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; Vivani's history of losses and Vivani's ability to access additional capital or otherwise fund Vivani's 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)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,646	$ 20,654
Prepaid expenses and other current assets	1,753	2,408
Total current assets	21,399	23,062
Property and equipment, net	1,644	1,729
Right-of-use assets	18,383	19,616
Restricted cash	1,338	1,338
Other assets	132	52
Total assets	$ 42,896	$ 45,797
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 815	$ 542
Accrued expenses	2,024	1,727
Litigation accrual	1,675	1,675
Accrued compensation expense	371	396
Current operating lease liabilities	1,385	1,383
Total current liabilities	6,270	5,723
Long-term operating lease liabilities	18,294	19,313
Total liabilities	24,564	25,036
Commitments and contingencies (Note 12)		
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: **55,266** and **51,031** at September 30, 2024 and December 31, 2023, respectively	6	5
Additional paid-in capital	134,108	119,054
Accumulated other comprehensive income	92	140
Accumulated deficit	(115,874)	(98,438)
Total stockholders' equity	18,332	20,761
Total liabilities and stockholders' equity	$ 42,896	$ 45,797

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development, net of grants	$ 4,203	$ 4,441	$ 11,442	$ 12,260
General and administrative, net of grants	2,106	2,703	6,775	8,488
Total operating expenses	6,309	7,144	18,217	20,748
Loss from operations	(6,309)	(7,144)	(18,217)	(20,748)
Other income, net	268	362	781	1,122
Net loss	$ (6,041)	$ (6,782)	$ (17,436)	$ (19,626)
Net loss per common share - basic and diluted	$ **(0.11)**	$ **(0.13)**	$ **(0.32)**	$ **(0.39)**
Weighted average common shares outstanding - basic and diluted	**55,247**	**50,837**	**54,161**	**50,757**

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