

Vivani Medical Provides Business Update and Reports Fourth Quarter and Full Year 2024 Financial Results

Successful initial administration and full enrollment in first-in-human LIBERATE-1™ study of NPM-115

(exenatide implant) in obese and overweight subjects with top-line data expected in mid-2025

Positive NPM-139 (semaglutide implant) preclinical weight loss data comparable to injections of semaglutide, active ingredient in Ozempic®/Wegovy®, with potential for once-yearly dosing

Additional \$8.25M equity financing which secures solid financial position into the second quarter of 2026,

supporting further development of NPM-139 and NPM-115 programs in chronic weight management

ALAMEDA, Calif., March 31, 2025 (GLOBE NEWSWIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), a biopharmaceutical company developing miniaturized, ultra long-acting drug implants including its lead assets NPM-115 (exenatide implant) and NPM-139 (semaglutide implant) 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, 2024, and provided a business update.

"During 2024, we transitioned Vivani to a clinical-stage biotechnology company and achieved significant milestones in both our NPM-115 and NPM-139 programs, both focused on transforming the treatment of chronic weight management targeting once or twice-yearly dosing," said Adam Mendelsohn, Ph.D., Vivani's Chief Executive Officer, "Our first-in-human LIBERATE-1 study continues to progress as planned with each implantation to date having been successful and we remain on track for top-line data in mid-2025. By providing key performance data on drug release, the value of LIBERATE-1 extends beyond the NPM-115 program by also informing the NPM-139 program as it advances in parallel."

Dr. Mendelsohn added, "In March, we raised funding to support operations into the second quarter of 2026. Additionally, we continue to equip our dedicated facility in Alameda, California, to support the manufacturing of large-scale clinical trial materials and, ultimately, commercial supply."

In response to the recent positive preclinical weight loss data with NPM-139, Vivani is now planning to advance NPM-139 towards clinical phase development in addition to the ongoing

Recent Business Highlights

On March 27, 2025, Vivani announced an \$8.25 million equity financing which secures solid financial position into the second quarter of 2026 and enables acceleration of priority development programs, including NPM-115 and NPM-139 for the treatment of obesity and chronic weight management.

On March 26, 2025, Vivani announced promising preclinical data for NPM-139, its subdermal semaglutide implant that is under development for chronic weight management in obese and overweight individuals. These results reinforce Vivani's commitment to addressing chronic weight management and other chronic diseases by leveraging its proprietary NanoPortal™ implant technology which is designed to enable smooth and steady delivery of therapeutic molecules including GLP-1 therapy. This development marks a significant advancement in improving medication adherence and patient convenience, addressing a critical gap in the treatment of chronic diseases including obesity and type 2 diabetes.

On March 13, 2025, Vivani also announced the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1 clinical trial. This milestone marks a critical step toward addressing one of healthcare's most pressing challenges: medication adherence in metabolic diseases involving chronic weight management and type 2 diabetes. The Company also announced full enrollment in the LIBERATE-1 study, which was achieved in just four weeks after enrollment of the first subject, signaling early potential interest for this six-month, subdermal GLP-1 implant and reaffirming previous estimates that top-line results should be available in mid-2025.

On March 12, 2025, the Company announced that it intends to spin off Cortigent, Inc. ("Cortigent"), a Delaware corporation and its wholly owned subsidiary, that develops brain implant devices to help people recover critical body functions, as an independent publicly traded company. The strategic goal of this transaction is to create two focused companies dedicated to driving current and future value in their respective therapeutic areas of expertise.

Moving forward, Vivani will focus on developing NPM-115, NPM-139 and its emerging pipeline of innovative miniature, ultra long-acting drug implants to treat patients with chronic diseases and high unmet medical need. The recent preclinical demonstration of NPM-139 comes on the heels of having rapidly enrolled and successfully administered the initial implants in LIBERATE-1, a first-in-human study with NPM-115, which is expected to pave the road for NPM-139 as development continues for both programs. Today, the Biopharm Division has grown to 35 full-time employees and its headquarters and operations are located at 1350 S. Loop Road, Alameda, California 94502.

Upcoming Anticipated Milestones

 Vivani anticipates the announcement of key milestones associated with the ongoing first-in-human LIBERATE-1 trial, including last subject implanted, and top-line results in mid-2025.

- Further announcements regarding the advancement of the NPM-139 program including projected timelines for filing an Investigational New Drug Application and pending regulatory clearance, initiation of an initial clinical trial.
- Vivani previously announced the submission of a Form S-1 registration statement to support an Initial Public Offering of Cortigent. This strategy has been revised to file a Form 10 registration statement with the U.S. Securities and Exchange Commission ("SEC") to enable the spin-off of Cortigent into a fully independent, publicly traded company subject to listing and regulatory requirements. Assuming successful financing is secured, Cortigent plans to continue advancing its pioneering precision neurostimulation technology intended to provide meaningful visual perception to blind individuals and to accelerate the recovery of arm and hand movement in patients suffering from paralysis due to stroke.

Fourth Quarter 2024 Financial Results

Note: Vivani (or the "Company") refers to the consolidated company including the Biopharm Division and Cortigent. The Biopharm Division refers to the drug implant business, the main focus of the consolidated company.

Cash Balance: As of December 31, 2024, Vivani had cash, cash equivalents and restricted cash totaling \$19.7 million, compared to \$22.0 million as of December 31, 2023. The decrease of \$2.3 million is primarily attributed to a net loss of \$23.5 million, and \$0.6 million related to purchase of equipment, which was mostly offset by net proceeds of \$19.1 million provided by the financing activities, non-cash items totaling \$2.3 million which includes stock-based compensation, depreciation and amortization of property and equipment, and lease expense.

Research and development expenses: Research and development expenses during the fourth quarter of 2024 were \$4.3 million, compared to \$4.7 million during the fourth quarter of 2023. The decrease of \$0.4 million, or 9%, was primarily attributable to staffing reduction and reduced use of outside services.

General and administrative expenses: General and administrative expenses during the fourth quarter of 2024 were \$2.1 million, compared to \$1.5 million during the fourth quarter of 2023. The increase of \$0.6 million, or 43%, was primarily attributable to increased professional services and stock-based compensation expense from the Biopharm Division.

Other income (expense): Other income (expense), net during the fourth quarter of 2024 was \$0.4 million, compared to \$0.2 million during the fourth quarter of 2023. The increase of \$0.2 million, or 124%, was primarily attributed to the tax credit earned on our Australian clinical trial investment.

Net Loss: The net loss during the fourth quarter of 2024 was \$6.1 million, compared to \$6.0 million during the fourth quarter of 2023. The change was insignificant.

Full Year 2024 Financial Results

Research and development expenses: Research and development expenses during the year ended December 31, 2024 was \$15.7 million, compared to \$17.0 million during the year

ended December 31, 2023. The decrease of \$1.2 million, or 7%, was primarily attributable to staffing reduction and reduced use of outside services from Cortigent, partially offset by the increase in our Biopharm Division's clinical trial related expenses.

General and administrative expenses: General and administrative expenses during the year ended December 31, 2024 was \$8.9 million, compared to \$10.0 million during the year ended December 31, 2023. The decrease of \$1.1 million, or 11%, was primarily attributable to staffing reductions along with reduced outside legal services from Cortigent, partially offset by the increase in the professional services of our Biopharm Division.

Other income (expense), net: Other income (expense), net during the year ended December 31, 2024 was \$1.2 million, compared to \$1.3 million during the year ended December 31, 2023. The change was insignificant.

Net Loss: The net loss during the year ended December 31, 2024 was \$23.5 million, compared to \$25.7 million during the year ended December 31, 2023. The decrease in net loss of \$2.2 million, or approximately 8%, was primarily attributable to staffing reduction and reduced use of outside services from Cortigent, partially offset by increased clinical trial related expenses and professional services from our Biopharm Division.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal platform, Vivani develops therapeutic 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 programs, NPM-139 (semaglutide implant) and NPM-115 (exenatide implant), are miniature, subdermal GLP-1 implants under development for chronic weight management in obese or overweight individuals designed for once or twice-yearly administration. Vivani's emerging pipeline also includes NPM-119, which refers to the Company's six-month, subdermal, GLP-1 (exenatide implant) under development for the treatment of type 2 diabetes. Development of a semaglutide implant for the treatment of type 2 diabetes is also under consideration. These NanoPortal implants are designed to provide patients with the opportunity to experience the full potential benefit of their medication by avoiding the challenges associated with the daily or weekly administration of oral and injectable medications.

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 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, ultra long-acting GLP-1 implants have the potential to provide an attractive therapeutic option for patients, prescribers and payers. For more information, please visit: www.vivani.com.

About Cortigent

Cortigent, formerly Second Sight Medical Products, Inc. and a wholly owned subsidiary of Vivani, is developing brain implant devices to help people recover critical body functions. Cortigent is a global leader in precision neurostimulation technology that provides meaningful visual perception ("artificial vision") for blind people. Cortigent previously marketed the Argus II, the first and only artificial vision device approved by the U.S. Food and Drug Administration ("FDA"), to treat a rare form of blindness. The Argus II has helped hundreds of profoundly blind people to achieve meaningful visual perception. Cortigent's next generation investigational system, the Orion, has been designed to treat blindness due to glaucoma, diabetic retinopathy, and other common causes. Orion has an FDA Breakthrough Device designation and in 2024, completed a 6-year Early Feasibility Study with encouraging safety and efficacy results. Cortigent's platform technology combines advanced neuroscience with proprietary microelectronics, software, and data processing capabilities to create medical devices for alleviating serious medical conditions that cannot be treated with drugs. It is protected by an extensive intellectual property estate. Cortigent is also applying its core precision neurostimulation technology to the recovery of arm and hand motion in paralysis due to stroke. For more information and patient videos, please visit: www.cortigent.com.

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. Forwardlooking 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 completion of the LIBERATE-1 trial and reporting of trial results, Vivani's emerging development plans for NPM-115, NPM-139, NPM-119, or Vivani's plans with respect to its wholly owned subsidiary Cortigent, and Vivani's 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, NPM-139, 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; 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 intended spin-off from the Company. 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 SEC filed on March 31, 2025, 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.

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VIVANI MEDICAL, INC. AND SUBSIDIARIES

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

	December 31,						
		2024	2023				
ASSETS	<u> </u>						
CURRENT ASSETS:							
Cash and cash equivalents	\$	18,352	\$	20,654			
R&D tax incentive receivable		253		_			
Prepaid expenses and other current assets		1,837		2,408			
Total current assets		20,442		23,062			
Property and equipment, net		1,693		1,729			
Operating lease right-of-use assets, net		17,957		19,616			
Restricted cash		1,338		1,338			
Deposits and other assets		131		52			
TOTAL ASSETS	\$	41,561	\$	45,797			
LIABILITIES AND STOCKHOLDERS' EQUITY	-						
CURRENT LIABILITIES:							
Accounts payable	\$	817	\$	542			
Accrued expenses		1,803		1,727			
Litigation accrual		1,675		1,675			
Accrued compensation expense		343		396			
Lease liability, current portion		1,348		1,383			
Total current liabilities		5,986		5,723			
Lease liability, noncurrent portion		17,965		19,313			
TOTAL LIABILITIES		23,951		25,036			
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: 59,235 and 51,031 as of December 31, 2024 and 2023,		6		5			
respectively Additional paid-in capital		139,480		119,054			
Accumulated other comprehensive gain		139,400		140			
Accumulated deficit		(121,924)		(98,438)			
TOTAL STOCKHOLDERS' EQUITY		17,610		20,761			
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	41,561	\$	45,797			

VIVANI MEDICAL, INC. AND SUBSIDIARIES

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

	Three Months Ended December 31,			Twelve Months Ended December 31,				
		2024		2023		2024		2023
Operating expenses:								
Research and development, net of grants	\$	4,297	\$	4,708	\$	15,745	\$	16,968
General and administrative, net of grants		2,163		1,509		8,932		9,997
Total operating expenses		6,460		6,217		24,677		26,965
Loss from operations		(6,460)		(6,217)		(24,677)		(26,965)
Other income (expense), net		410		191		1,191		1,313
Net loss	\$	(6,050)	\$	(6,026)	\$	(23,486)	\$	(25,652)
Net loss per common share - basic and diluted	\$	(0.11)	\$	(0.12)	\$	(0.43)	\$	(0.50)
Weighted average shares outstanding - basic and diluted		57,423		51,025		54,981		50,853



Source: Vivani Medical, Inc.