

Vivani Medical Provides Business Update Including \$3M Equity Financing and Reports First Quarter 2025 Financial Results

All subjects in the NPM-115 cohort had successful insertions of a miniature, ultra long-acting GLP-1 (exenatide) implant in the on-going LIBERATE-1™ study in obese or overweight individuals; top-line results are anticipated in mid-2025

Announced new \$3M equity financing together with the previously reported \$8.25M equity financing secures financial position into mid-2026

Promising pre-clinical data released for NPM-139 (semaglutide implant) for chronic weight management in obese and overweight patients

Company plans to spin off Cortigent, Inc., a division that develops brain implant devices to help patients recover critical body functions, as an independent publicly traded company

ALAMEDA, Calif., May 13, 2025 (GLOBE NEWSWIRE) -- <u>Vivani Medical, Inc.</u> (Nasdaq: <u>VANI</u>) ("Vivani" or the "Company"), a biopharmaceutical company developing miniaturized, ultra long-acting drug implants, today reported financial results for the first quarter ended March 31, 2025, and provided a business update including a \$3M equity financing.

Vivani Chief Executive Officer Adam Mendelsohn, Ph.D., stated, "Our ongoing first-in-human study, LIBERATE-1, remains on track to deliver key data in mid-2025 with the aim of validating our proprietary NanoPortal™ implant technology and enabling us to advance our portfolio of exenatide and semaglutide based drug implants in clinical development. The study enrolled ahead of schedule, and all NPM-115 (exenatide implant) insertions were successful."

Dr. Mendelsohn added, "While the GLP-1 market continues to grow and mature, it is clear that meaningful differentiation will be required for commercial success of new market entrants, in part because of the significant clinical benefits delivered by the currently available GLP-1 therapies. We remain confident that our emerging portfolio of convenient, miniature, subdermal drug implants with once- or twice-yearly dosing will stand out as a highly differentiated and sought-after alternative GLP-1 treatment option for patients and providers, with the potential to substantially improve patient outcomes by addressing poor medication adherence and patient tolerability."

Recent Business Highlights

On May 12, 2025, Vivani announced that it has entered into a securities purchase agreement to issue and sell an aggregate of 2,912,621 shares, each at a price of \$1.03 per share, expected to result in gross proceeds of approximately \$3.0 million in a private placement.

On April 15, 2025, Vivani and Okava Pharmaceuticals, Inc. ("Okava"), a clinical-stage company focused on the treatment of age-related diseases in dogs and cats, announced an expansion of their collaboration focused on cats that was initiated in 2019, to now include dogs in the development of OKV-119, a long-acting GLP-1 therapy that leverages Vivani's NanoPortal technology for weight management, diabetes and other cardiometabolic conditions

On March 27, 2025, Vivani announced that it has entered into a securities purchase agreement to issue and sell an aggregate of 7,366,071 shares, each at a price of \$1.12 per share, expected to result in gross proceeds of approximately \$8.25 million in a private placement.

On March 26, 2025, Vivani announced promising preclinical data for NPM-139, its subdermal semaglutide implant under development for chronic weight management in obese and overweight individuals. These results reinforce the Company's commitment to addressing chronic weight management and other chronic diseases by leveraging its NanoPortal implant technology designed to enable smooth and steady delivery of therapeutic molecules, including GLP-1 therapy.

On March 13, 2025, Vivani announced the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1 clinical trial. This milestone marked a critical step toward addressing one of healthcare's most pressing challenges: medication adherence in the treatment of metabolic diseases including 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 exenatide implant and reaffirming previous estimates that top-line results should be available in mid-2025.

On March 12, 2025, Vivani announced that it intends to spin off Cortigent, Inc., a division of the Company that develops brain implant devices to help patients recover critical body functions, as an independent publicly traded company. The strategic goal of this transaction intends to create two companies that are focused and dedicated to driving current and future value in their respective therapeutic areas of expertise.

Upcoming Anticipated Milestones

- Vivani anticipates top-line data from the LIBERATE-1 study in mid-2025. LIBERATE-1
 is a Phase 1 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.
- Vivani plans to participate in the BIO International Convention hosted in Boston, MA from June 16 to 19, 2025. Dr. Mendelson will provide a Company presentation during the Convention, in addition to participating in partnering activities with potential

investors and strategic partners alongside Vivani Chief Business Officer Don Dwyer.

First Quarter 2025 Financial Results

Cash balance: As of March 31, 2025, Vivani had cash, cash equivalents and restricted cash totaling \$14.3 million, compared to \$19.7 million as of December 31, 2024. The decrease of \$5.4 million is attributed to a net loss of \$6.3 million, partially offset by a \$0.6 million net change to 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 expenses.

Research and development expense: Research and development expense during the three months ended March 31, 2025 was \$4.2 million, compared to \$3.7 million during the three months ended March 31, 2024. The increase of \$0.5 million, or 13%, was primarily attributable to increased research and development expenses from our Biopharma division.

General and administrative expense: General and administrative expense during the three months ended March 31, 2025 was \$2.3 million, compared to \$2.5 million during the three months ended March 31, 2024. The decrease of \$0.2 million, or 6%, was attributable to reduced professional services and personnel expenses from our Biopharma division.

Other income, net: Other income, net during the three months ended March 31, 2025 was \$0.3 million, compared to \$0.2 million during the three months ended March 31, 2024. The change was not significant.

Net Loss: The net loss during the three months ended March 31, 2025 was \$6.3 million, compared to \$6.0 million during the three months ended March 31, 2024. The increase in net loss of \$0.3 million was primarily attributable to an increase in operating expenses of \$0.3 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 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 subjects. Vivani's emerging pipeline also includes 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 onceyearly dosing. 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. 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 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 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 (unaudited)

(in thousands, except per share data)

		March 31, 2025		December 31, 2024	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	13,008	\$	18,352	
R&D tax credit incentive receivable		175		253	
Prepaid expenses and other current assets		1,667		1,837	
Total current assets		14,850		20,442	
Property and equipment, net		1,609		1,693	
Operating lease right-of-use assets, net		17,523		17,957	
Restricted cash		1,338		1,338	
Other assets		132		131	
Total assets	\$	35,452	\$	41,561	
LIABILITIES AND STOCKHOLDERS' EQUITY	<u></u>		i 		
Current liabilities:					
Accounts payable	\$	1,004	\$	817	
Accrued expenses		1,859		1,803	
Litigation accrual		1,675		1,675	
Accrued compensation expense		350		343	
Current operating lease liabilities		1,311		1,348	
Total current liabilities		6,199		5,986	
Long-term operating lease liabilities		17,629		17,965	
Total liabilities		23,828		23,951	
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: 59,244 and 59,235 at March 31, 2025 and December 31,		6		6	
2024, respectively Additional paid-in capital		139,802		139,480	
Accumulated other comprehensive income		42		48	
Accumulated other comprehensive income Accumulated deficit		(128,226)		(121,924)	
Total stockholders' equity	-	11,624		17,610	
• •	\$	35,452	\$	41,561	
Total liabilities and stockholders' equity	Ψ	33,432	Ψ	41,501	

VIVANI MEDICAL, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except per share data)

	Three Months Ended March 31,			
	2025		2024	
Operating expenses:				
Research and development, net of grants	\$	4,217	\$	3,726
General and administrative, net of grants		2,340		2,501
Total operating expenses		6,557		6,227
Loss from operations	'	(6,557)		(6,227)
Other income, net		255		188
Net loss	\$	(6,302)	\$	(6,039)
Net loss per common share - basic and diluted	\$	(0.11)	\$	(0.12)
Weighted average common shares outstanding - basic and diluted		59,236		52,202



Source: Vivani Medical, Inc.