May 15, 2023

Vivani Medical Reports First Quarter Financial Results and Provides Business Update

EMERYVILLE, Calif.--(BUSINESS WIRE)-- Vivani Medical, Inc. (Nasdaq: VANI) (“Vivani” or the “Company”), a biopharmaceutical company developing miniaturized, long-term drug implants, including lead product NPM-119 for the treatment of patients with type 2 diabetes and/or obesity, today reported financial results for the first quarter and provided a business update. NPM-119 is a preclinical stage, 6-month, GLP-1 implant using Vivani’s proprietary NanoPortal™ implant technology.

Vivani continues to advance the development of its emerging portfolio of innovative, highly differentiated drug implants leveraging its proprietary NanoPortal™ subdermal implant technology designed to guarantee medication adherence and improve patient outcomes in the treatment of chronic diseases.

Adam Mendelsohn, Chief Executive Officer said, “Vivani remains on schedule with the planned submission of an Investigational New Drug (IND) application for NPM-119 (GLP-1 implant) and the subsequent initiation of the proposed first-in-human Phase 2 clinical study of NPM-119, 'LIBERATE-1, in mid-2023.” Dr. Mendelsohn further commented, “We believe that NPM-119 has the potential to significantly improve real-world outcomes for the approximately half of patients with type 2 diabetes who are non-adherent with their medication. We further believe that NPM-119 may also provide an improved gastrointestinal side-effect profile compared to other available GLP-1 treatment options because of NPM-119’s steady drug delivery profile.” The LIBERATE-1 trial will be the first clinical study of the company’s platform NanoPortal implant technology.

First Quarter Business Highlights

In January 2023, Vivani successfully completed the IND-enabling, non-clinical toxicology, and biocompatibility studies to support the planned IND submission for NPM-119 (exenatide implant) under development for the treatment of patients with type 2 diabetes. By mid-2023, we plan to file an IND with the U.S. Food and Drug Administration (the “FDA”) and, if clearance is obtained, initiate LIBERATE-1. LIBERATE-1 is a randomized, 12-week investigation of the safety, tolerability, and full pharmacokinetic profile of NPM-119 (GLP-1) implant in patients with type 2 diabetes. LIBERATE-1 will enroll patients who have been on a GLP-1 therapy which will be discontinued prior to receiving either NPM-119 or an active comparator Bydureon BCise® (exenatide extended-release injectable suspension 2mg). LIBERATE-1 will also evaluate the treatment effects on glycemic control and weight, and the inclusion of the active comparator is intended to explore the feasibility of an abbreviated 505(b)(2) approval pathway for NPM-119.

In March 2023, Vivani announced the filing of a Registration Statement on Form S-1 with the U.S. Securities and Exchange Commission ("SEC") for the proposed initial public offering of Cortigent, Inc. ("Cortigent"). Cortigent was formed for the purpose of advancing Vivani's neuromodulation division and is expected to continue to be controlled by Vivani after the initial public offering.

Moving forward, Vivani will focus on its Biopharm Division and the further development of NPM-119 and its emerging pipeline of innovative, miniature, long-term drug implants to treat patients with chronic diseases and high unmet medical need. Vivani's Biopharm Division has grown to nearly 40 full-time employees. Its headquarters are located at 5858 Horton Street, Emeryville, California.

Upcoming Anticipated Milestones and Events

We expect to file the NPM-119 (GLP-1 implant) IND with the FDA and, subject to IND clearance, we intend to initiate LIBERATE-1 in Q3-2023 and expect to report top-line results in the first half of 2024.

In addition, we are seeking to complete the Initial Public Offering for our Cortigent business in the third quarter of 2023 enabling us to continue advancing our neuromodulation technology.

We will also be participating in several investor conferences and attending key industry conferences including the 2023 BIO International Convention June 5-8, 2023, in Boston MA and the American Diabetes Association 83rd Scientific Sessions June 23-26, 2023, in San Diego, CA.

First Quarter 2023 Financial Results

Cash Balance: As of March 31, 2023, Vivani had cash and cash equivalents totaling $38.1 million compared to $45.1 million as of December 31, 2022. The decrease is attributed to the $6.3 million operating loss plus a reduction of working capital of $1.1 million, offset partially by $0.4 million of non-cash expenses. We believe our cash and cash equivalents as of March 31, 2023, are sufficient to fund operations into the second half of 2024.

Research and Development Expense: Research and development expense increased by $1.3 million, or 48%, to $4.0 million in the first quarter of 2023 from $2.7 million in the first quarter of 2022. The costs increased due to costs of our acquired company, Second Sight, being included from the merger acquisition date of August 30, 2022. This inclusion increased costs for the quarter by $0.6 million. The remainder of the increase was primarily due to subdermal drug implants development costs.

General and Administrative Expense: General and administrative expenses increased $1.4 million, or 115%, to $2.6 million in the first quarter of 2023 from $1.2 million in the same period of 2022. This increase is primarily attributable to increased costs associated with the inclusion of our acquired company Second Sight which totaled $1.1 million in the first quarter of 2023.

Operating Expense: Operating expenses were $6.6 million for the three months ended March 31, 2023, compared to $3.9 million for the three months ended March 31, 2022,

representing an increase of $2.7 million, or 69%. The inclusion of Second Sight costs for the first quarter of 2023 totaled $1.7 million.

Net Loss: The net loss was $6.3 million as compared to $3.9 million for the three-months ended March 31, 2023, and 2022, respectively. The $2.4 million increase in net loss was primarily attributable to a $2.7 million increase in operating expenses, as noted above, partially offset by an increase of $0.3 million in interest income due to our higher cash balance.

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 tolerance to their medication. Vivani's lead program NPM-119 is a miniaturized, 6-month GLP-1 implant under investigation for the treatment of patients with type 2 diabetes and/or obesity. NPM-119 is 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 US alone, is a primary and daunting reason why type 2 diabetes treatments face significant challenges in achieving positive real-world effectiveness.

Vivani's wholly owned subsidiary Cortigent, Inc., has developed, manufactured, and marketed implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. Cortigent continues to assess strategic options for advancing its pioneering neuromodulation technology including the Orion® Visual Cortical Prosthesis System for providing artificial vision to profoundly blind individuals and a new medical device system to improve the recovery of hand and arm movement in partially paralyzed stroke patients undergoing rehabilitation.

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, products in development, including the therapeutic potential thereof and the planned development therefor, our 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 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 products, including 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 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 Securities and Exchange Commission (the "Commission") filed on March 31, 2023. 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)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,073	$ 45,076
Prepaid expenses and other current assets	2,611	2,452
Total current assets	40,684	47,528
Property and equipment, net	1,111	1,182
Right-of-use assets	1,148	779
Restricted cash	1,366	1,366
Deposits and other assets	271	275
Total assets	$ 44,580	$ 51,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 746	$ 1,177
Accrued expenses	2,114	2,358
Litigation accrual	1,675	1,675
Accrued compensation expense	415	657
Current operating lease liabilities	913	955
Total current liabilities	5,863	6,822
Long term operating lease liabilities	349	—
Total liabilities	6,212	6,822
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding: 50,789 as of March 31, 2023 and 50,736 as of December 31, 2022, respectively	109,050	109,050
Additional paid-in capital	8,378	8,009
Accumulated other comprehensive loss	44	35
Accumulated deficit	(79,104)	(72,786)
Total stockholders' equity	38,368	44,308
Total liabilities and stockholders' equity	$ 44,580	$ 51,130

VIVANI MEDICAL, INC.
AND SUBSIDIARIES
Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development, net of grants	$ 3,955	$ 2,679
General and administrative, net of grants	2,646	1,228
Total operating expenses	6,601	3,907
Loss from operations	(6,601)	(3,907)
Other income (expense), net	283	(17)
Net loss	$ (6,318)	$ (3,924)
Net loss per common share – basic and diluted	$ (0.12)	$ (0.11)
Weighted average common shares outstanding – basic and diluted	50,755	36,806

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