August 14, 2023

Vivani Medical Reports Second Quarter Financial Results and Provides Business Update

EMERYVILLE, Calif.--(BUSINESS WIRE)-- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), an innovative, preclinical-stage biopharmaceutical company developing novel, long-term drug implants, today reported financial results for the second quarter of 2023 and provided a business update.

Vivani™ continues to advance 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. Vivani's lead therapeutic candidate, NPM-119, is a miniature, six-month, GLP-1 implant using NanoPortal technology.

"At Vivani, we are continuing our progression from a preclinical to clinical-stage biopharmaceutical company. As planned, we have successfully completed the production of clinical trial materials and submitted our Investigational New Drug (IND) application for NPM-119 (exenatide implant) in July. Although we received verbal notification from the U.S. Food and Drug Administration (FDA) that our NPM-119 IND will be placed on clinical hold, we await the receipt of FDA's comments and intend to respond to the agency's requests with the goal of achieving IND clearance and proceeding with our plans to initiate the proposed first-in-human, Phase 2 clinical study of NPM-119 named LIBERATE-1™," said Adam Mendelsohn, Ph.D., Vivani's President and Chief Executive Officer. "LIBERATE-1 represents the first clinical application of our NanoPortal technology and is designed to evaluate the safety, tolerability and full pharmacokinetic profile of NPM-119 compared to an active control group. The study will also evaluate glycemic control and weight-loss information and we aim to better understand the translation of drug release profiles from our animal models to patients with type 2 diabetes which will inform the development of NPM-119 and our emerging portfolio of long-term drug implants with the potential to revolutionize chronic disease treatments."

Second Quarter Business Highlights

In early July 2023, Vivani successfully completed the manufacture of clinical supplies to support a proposed first-in-human ("FIH") investigation of NPM-119 in patients with type 2 diabetes mellitus. On July 14, 2023, the Company submitted an IND application to the FDA for the proposed NPM-119 FIH study also named LIBERATE-1.

On August 11, 2023, the FDA verbally notified Vivani that the agency was placing a clinical hold on Vivani's IND application for the proposed LIBERATE-1 study and indicated its

intention to subsequently provide an official clinical hold letter stating the reasons for the clinical hold. Vivani plans to engage with the FDA in order to lift the clinical hold and commence its planned clinical development of NPM-119. The Company expects to commence enrollment in LIBERATE-1 in the second half of 2023 subject to regulatory clearance. Assuming LIBERATE-1 commences as planned, the Company would anticipate the availability of interim LIBERATE-1 data in the first half of 2024 and full top-line results in the second half of 2024.

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 the 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.

On July 6, 2023, Vivani changed its state of incorporation from the State of California to the State of Delaware by means of a plan of conversion, effective July 5, 2023. The reincorporation, including the principal terms of the plan of conversion, was submitted to a vote of, and approved by Vivani's stockholders at its 2023 Annual Meeting of Stockholders held on June 15, 2023.

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"), a wholly owned subsidiary of Vivani. Cortigent was formed for the purpose of advancing Vivani's neuromodulation division and is expected to continue to be controlled by Vivani after its initial public offering.

Moving forward, Vivani will focus on the further development of NPM-119 and its emerging pipeline of innovative, miniature, long-term drug implants to treat patients with chronic diseases. Vivani's Biopharm Division has grown to approximately 35 full-time employees and its headquarters are currently in Emeryville, California.

Upcoming Anticipated Milestones and Events

The Company expects to commence enrollment of patients in LIBERATE-1, its Phase 2 trial of NPM-119 in patients with type 2 diabetes, in the second half of 2023 subject to regulatory clearance. Assuming LIBERATE-1 commences as planned, the Company would anticipate the availability of interim LIBERATE-1 data in the first half of 2024 and full top-line results in the second half of 2024.

Vivani expects Cortigent's initial public offering to enable further advancement of its neuromodulation technology.

Vivani plans to move its corporate headquarters and operations to a new facility located in Alameda, California in the second half of 2023. This facility can support Vivani's future growth including commercial manufacturing.

Second Quarter ended June 30, 2023, Financial Results

Cash Balance: As of June 30, 2023, Vivani had cash and cash equivalents totaling $32.5 million compared to $45.1 million as of December 31, 2022. The decrease of $12.6 million is attributed to the $12.8 million operating loss plus a net increase in net operating assets of $0.9 million, offset partially by $1.2 million of non-cash charges. The Company believes its cash and cash equivalents as of June 30, 2023, are estimated to be sufficient to fund operations until at least September 2024.

Research and development expense: Research and development expense increased by $0.7 million, or 21%, to $3.9 million in the second quarter of 2023 from $3.2 million in the second quarter of 2022. The costs increased due to costs of Vivani's acquired company Cortigent being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the quarter by $0.5 million. The remainder of the increase was primarily due to drug implant development costs.

General and administrative expense: General and administrative expense increased $2.2 million, or 255%, to $3.1 million in the second quarter of 2023 from $0.9 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of Vivani's acquired company Cortigent which totaled $1.0 million in the second quarter of 2023, higher costs associated with being a public company of $0.9 million for D&O insurance and professional fees, and payroll related expenses. Approximately $0.2 million of costs were incurred related to the Cortigent IPO in the quarter.

Other income: Other income was impacted by the merger acquisition of cash which increased the Company's interest income by $0.5 million for the three months ended June 30, 2023, as compared to the same period in 2022 before the merger.

Net Loss: The net loss was $6.5 million as compared to $4.1 million for the three-months ended June 30, 2023, and 2022, respectively. The $2.4 million increase in net loss was primarily attributable to a $1.5 million increase from the inclusion of Cortigent which was not included in 2022 prior to the merger, and increased salaries and costs of being a public company.

Year to Date June 30, 2023, Financial Results

Research and development expense: Research and development expense increased by $1.9 million, or 33%, to $7.8 million in the first six months of 2023 from $5.9 million in the same period of 2022. The costs increased due to costs of Vivani's acquired company Cortigent being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the period by $1.2 million. The remainder of the increase was primarily due to drug implants development costs.

General and administrative expense: General and administrative expense increased $3.7 million, or 174%, to $5.8 million in the first six months of 2023 from $2.1 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of Vivani's acquired company Cortigent which totaled $2.1 million in the first six months of 2023, higher public company costs of $1.0 million, and higher payroll related expenses. Approximately $0.3 million of costs were incurred related to the Cortigent IPO in the period.

Other income: Other income was impacted by the merger acquisition of cash which

increased the Company's interest income to $0.7 million for the six months ended June 30, 2023, as compared to the same period in 2022 before the merger.

Net Loss: The net loss was $12.8 million as compared to $8.0 million for the six-months ended June 30, 2023, and 2022, respectively. The $4.8 million increase in net loss was primarily attributable to a $3.3 million increase from the inclusion of Cortigent, which was not included in 2022 prior to the merger, and increased salaries and costs of being a public company.

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-119 is a miniaturized, 6-month GLP-1 implant under investigation for the treatment of patients with type 2 diabetes and is also under consideration for the treatment of 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 U.S. 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, formed to continue the business of Second Sight, is developing targeted 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. The company 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 our business, products in development, including the therapeutic potential thereof, the planned development therefor, plans to address any requests from the FDA related to the agency's clinical hold on the LIBERATE-1 trial, the initiation of LIBERATE-1 and reporting of trial results, 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 the development of our 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 address any requests from the FDA in related to LIBERATE-1 and to commence clinical development of NPM-119; 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 SEC filed on March 31, 2023, as updated by our subsequent Quarterly Reports on Form 10-Q. 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 except per share data)

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,486	$ 45,076
Prepaid expenses and other current assets	3,736	2,452
Total current assets	36,222	47,528
Property and equipment, net	1,075	1,182
Right-of-use assets	20,684	779
Restricted cash	1,366	1,366
Deposits and other assets	260	275
Total assets	$ 59,607	$ 51,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,989	$ 1,177
Accrued expenses	1,994	2,358
Litigation accrual	1,675	1,675
Accrued compensation expense	567	657
Current operating lease liabilities	861	955
Total current liabilities	7,086	6,822
Long term operating lease liabilities	20,127	—
Total liabilities	27,213	6,822
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, par value $0.0001 per share; 300,000 shares authorized; shares issued and outstanding: 50,799 as of June 30, 2023 and 50,736 as of December 31, 2022, respectively	5	5
Additional paid-in capital	117,954	117,054
Accumulated other comprehensive loss	65	35
Accumulated deficit	(85,630)	(72,786)
Total stockholders' equity	32,394	44,308
Total liabilities and stockholders' equity	$ 59,607	$ 51,130

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

	For the Three Months ended June 30,		For the Six Months ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development, net of grants	$ 3,864	$ 3,203	$ 7,819	$ 5,883
General and administrative	3,139	884	5,785	2,112
Total operating expenses	7,003	4,087	13,604	7,995
Loss from operations	(7,003)	(4,087)	(13,604)	(7,995)
Other income (expense), net	477	(16)	760	(33)
Net income/(loss)	$ (6,526)	$ (4,103)	$ (12,844)	$ (8,028)
Net income/(loss) per common share – basic	$ (0.13)	$ (0.11)	$ (0.25)	$ (0.22)
Weighted average common shares outstanding – basic	50,795	36,880	50,748	36,819

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

Investor Relations Contact:
Brigid A. Makes
Chief Financial Officer
investors@vivani.com
(415) 506-8462

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

Source: Vivani Medical, Inc.