

March 31, 2023



Vivani Medical Reports Fourth Quarter and Full Year 2022 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 candidate NPM-119 for the treatment of patients with type 2 diabetes, today reported financial results for the fourth quarter and full year ended December 31, 2022, and provided a business update.

According to Adam Mendelsohn, Chief Executive Officer, "2022 was truly a transformational year for the Company, including the business combination of Nano Precision Medical ("NPM") and Second Sight Medical Products ("Second Sight"), into our newly merged company, Vivani Medical, Inc. We made significant progress with our lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes using our proprietary NanoPortal™ implant technology. We continue to 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 also believe that NPM-119 has the potential to demonstrate an improved gastrointestinal side-effect profile compared to other available GLP-1 treatment options because of NPM-119's steady drug delivery profile. After successful completion of the non-clinical toxicology and other supportive studies, we plan to submit an Investigational New Drug ("IND") application and initiate our proposed first-in-human, randomized, Phase 2 clinical trial, named LIBERATE-1, in mid-2023. After years of development, it is very exciting to be approaching the first clinical application of our proprietary NanoPortal implant platform technology."

Dr. Mendelsohn further added, "I am also very proud of the significant progress achieved by our Neuromodulation Division, now known as Cortigent Inc., in collaboration with our new leadership team in identifying strategic options to support the further development of the division's pioneering neurostimulation systems aimed at helping patients recover critical body functions."

Recent Business Highlights

In July 2022, Vivani generated encouraging 6-month, preclinical, proof-of-concept data using a prototype implant configuration that we plan to develop and evaluate further in the clinical setting.

In August 2022, the business combination of Second Sight and NPM was completed, and the combined company was renamed Vivani. Since the business combination, Vivani's main

priority has been the further development of the Company's lead program, NPM-119, a miniature, 6-month, GLP-1 implant candidate for the treatment of patients with type 2 diabetes under the Company's Biopharm Division (formerly NPM). In parallel, Vivani's new management team remains committed to identifying and exploring strategic options for the Neuromodulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems.

In November 2022, Vivani's neuromodulation business was established as a wholly-owned subsidiary named Cortigent, Inc., a Delaware corporation.

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 the IND with the U.S. Food and Drug Administration (the "FDA") and, if clearance is obtained, initiate our first-in-human, randomized, 12-week, Phase 2 clinical trial of NPM-119 (exenatide implant) in patients with type 2 diabetes, which we have designated as LIBERATE-1. The primary objective will be investigation of the safety, tolerability, and full pharmacokinetic profile of NPM-119. Bydureon Bcise® (exenatide extended-release injectable suspension) will also be included in the trial as an active comparator. Secondary objectives will include glycemic lowering and the study will also be evaluating changes in weight.

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 following the initial public offering.

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

Upcoming Anticipated Milestones

We anticipate the filing of the NPM-119 (exenatide implant) IND with the FDA and, subject to IND clearance, we anticipate initiating LIBERATE-1 in mid-2023, and expect to report top-line results in the first half of 2024.

2022 Financial Results

Cash Balance: As of December 31, 2022, Vivani had cash and cash equivalents totaling \$45.1 million compared to \$2.2 million in year ended December 31, 2021, and cash and cash equivalents of \$51.7 million as of September 30, 2022. The increase is attributed to the \$55.4 million that was consolidated as a result of the merger with Second Sight. We believe our cash and cash equivalents as of December 31, 2022, are sufficient to fund operations into the second half of 2024.

Research and Development Expense: Research and development expenses increased from

\$11.0 million in 2021 to \$14.2 million in 2022, an increase of \$3.2 million, or 29%. The increase from the prior year was primarily due to increased use of outside contractors associated with product design, development and manufacturing associated with our products, increased headcount and professional fees, along with inclusion of new neuromodulation division costs.

General and Administrative Expense: General and administrative expenses increased from \$2.3 million in 2021 to \$7.1 million in 2022, an increase of \$4.8 million, or 205%. The increase is related to a provision for a legal claim of \$1.7 million and increased accounting and legal costs and other expenses related to our merger of approximately \$1.5 million and the general and administrative costs of the neuromodulation division since the merger of \$1.1 million.

Operating Expense: Operating expenses were \$21.2 million for the year ended December 31, 2022, compared to \$13.3 million for the year ended December 31, 2021, representing an increase of \$7.9 million, or 59%.

Net Loss: The net loss was \$13.9 million in 2022, as compared to \$12.8 million in 2021. The \$1.1 million increase in net loss from 2021 to 2022 was primarily attributable to a \$7.9 million increase in operating expenses offset by a \$6.9 million gain on the bargain purchase and increased interest income due to rate increases on cash investments.

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 patient adherence to their medication. Vivani's lead program, which is under development within our Biopharm Division, is NPM-119, a miniaturized, 6-month GLP-1 implant under investigation for the treatment of patients with type 2 diabetes. NPM-119 is designed to provide patients with the opportunity to realize the full potential benefit of their medication while avoiding the challenges associated with the daily or weekly administration of oral and injectable products. Medication non-adherence occurs when patients do not take their medication as prescribed. This affects an alarmingly substantial number of patients, approximately 50%, including those taking daily pills. Medication non-adherence, which contributes to more than \$500 billion in avoidable healthcare costs and 125,000 potentially preventable deaths per year in the US alone, is a primary reason why type 2 diabetes treatments face significant challenges in achieving positive real-world effectiveness. Vivani's Neuromodulation Division, recently incorporated as the 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 Orion II, a visual prosthetic device designed to treat profound blindness and other applications of its pioneering neurostimulation 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, product candidates,

including the therapeutic potential thereof and the planned development therefor, technology and strategy. 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 product candidates, 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 achieve or sustain profitability in the future; and the impact of COVID-19 on our business. 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”), and the Company’s final proxy statement/prospectus filed with the Commission on June 24, 2022. 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**

Consolidated Balance Sheets
(In thousands)
(Unaudited)

	December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 45,076	\$ 2,178
Prepaid expenses and other current assets	2,452	291
Total current assets	47,528	2,469
Property and equipment, net	1,182	1,173
Right-of-use asset	779	1,611
Restricted cash	1,366	—
Deposits and other assets	275	200
Total assets	<u>\$ 51,130</u>	<u>\$ 5,453</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,177	\$ 281
Accrued expenses	2,358	895
Litigation accrual	1,675	—
Accrued compensation expense	657	—
Current operating lease liabilities	955	910
Total current liabilities	6,822	2,086
Long term operating lease liabilities	—	902
Total liabilities	6,822	2,988
Commitments and contingencies (Note 12)		
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: 50,736 and 36,803 at December 31, 2022 and December 31, 2021, respectively	109,050	54,649
Additional paid-in capital	8,009	6,713
Accumulated other comprehensive loss	35	—
Accumulated deficit	(72,786)	(58,897)
Total stockholders' equity	44,308	2,465
Total liabilities and stockholders' equity	<u>\$ 51,130</u>	<u>\$ 5,453</u>

**VIVANI MEDICAL, INC.
AND SUBSIDIARIES**

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

	Years Ended December 31,	
	2022	2021
Operating expenses:		
Research and development, net of grants	\$ 14,169	\$ 11,002
General and administrative, net of grants	7,072	2,321
Total operating expenses	21,241	13,323
Loss from operations	(21,241)	(13,323)
Other income	475	550
Gain on bargain purchase	6,877	—
Net loss	\$ (13,889)	\$ (12,773)
Net loss per common share – basic and diluted	\$ (0.36)	\$ (0.39)
Weighted average shares outstanding – basic and diluted	38,241	33,092

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