

Vivani Medical Reports Third Quarter 2022 Results and Provides Business Updates

EMERYVILLE, Calif.--(BUSINESS WIRE)-- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), a biopharmaceutical company developing miniaturized, long-term drug implants including lead asset NPM-119 for the treatment of patients with type 2 diabetes, today announced financial results for the third quarter ending September 30, 2022 and provides business updates.

Recent Business Highlights

 The merger of Second Sight Medical Products, Inc. and Nano Precision Medical, Inc. closed on August 30, 2022. Concurrent with the Merger, the combined company changed its name to Vivani Medical, Inc. and trades under the ticker VANI on the Nasdaq Capital Market.

Biopharm Division NPM-119 (GLP-1 receptor agonist implant)

- Recent extensive studies have confirmed the excellent biocompatibility of NPM-119's device constituent.
- Successfully completed an IND-enabling non-clinical toxicology study.
- Initiated GMP manufacturing of clinical trial supplies for planned Phase 2 study designated as LIBERATE-1.
- On track for IND filing and LIBERATE-1 study initiation in early 2023. LIBERATE-1 is
 designed as a 12-week, randomized, multiple-dose, first-in-human clinical trial of NPM119. Its primary objectives are to assess safety and tolerability and full
 pharmacokinetic characterization, with a secondary objective to evaluate change from
 baseline in glycemic control.
- Top-line results from LIBERATE-1 anticipated in late 2023.
- Achieved 6-month NPM-119 preclinical proof-of-concept.

Pipeline

 Demonstrated feasibility of companion feline program OKV-119 which is now advancing into preclinical development with partner Okava Pharma.

Neuromodulation Division Orion (cortical implant)

- Exploring strategic options to support advancement of this innovative technology.
- Developing improved customer support proposals for legacy product customers.

"I am delighted with the progress of both the Biopharm and Neuromodulation divisions at Vivani and I am very excited as we make our final preparations to enable initiation of the LIBERATE-1 study, which represents our first opportunity to investigate the performance of our GLP-1 implant candidate in patients with type 2 diabetes early next year," said Adam Mendelsohn, Chief Executive Officer. "As a result of the merger, we believe we are well positioned with our experienced leadership and sufficient capital to support multiple milestones for NPM-119 while we continue to assess the strategic options for advancing Orion II."

Third Quarter 2022 Financial Results

Research and development expenses were \$3.9 million in the third quarter of 2022, compared to \$2.9 million in the third quarter of 2021. The increase was primarily due to higher product development activities and higher personnel costs as a result of increased headcount associated with the merger.

General and administrative expenses were \$1.6 million in the third quarter of 2022, compared to \$0.6 million in the third quarter of 2021. The increase was the result of higher headcount associated with the merger, higher stock-based compensation expenses and an increase in costs associated with being a public company.

Operating expenses were \$5.4 million in the third quarter of 2022, compared to \$3.5 million in the third quarter of 2021, representing an increase of 56%.

Net income was \$1.4 million in the third quarter of 2022, compared to a net loss of \$3.5 million in the third quarter of 2021. The variance was primarily due to a net bargain purchase gain of \$6.9 million associated with the valuation of the merger.

As of September 30, 2022, cash and cash equivalents were \$51.7 million, and we estimate that these cash resources are sufficient to fund planned operations into the second half of 2024.

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 hassles 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 significant number of patients, approximately 50%, including those taking daily pills. Medication non-adherence, which contributes to more than \$500B in avoidable healthcare costs and 125,000 potentially preventable deaths per year in the U.S. alone, is a primary reason why Type 2 diabetes treatments face significant challenges in achieving positive real-world effectiveness. Vivani's Neuromodulation Division has developed, manufactured, and marketed implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. Vivani continues to assess strategic options for advancing Orion II, a visual prosthetic device

designed to treat profound blindness. For more information, please visit www.vivani.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 our business, product candidates, including the therapeutic potential thereof and the planned development therefor, our planned LIBERATE-1 clinical trial, timing of its initiation and expected results therefrom, technology and strategy, financial position, and cash 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 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 Quarterly Report on Form 10-Q, and any subsequent quarterly filings on Form 10-Q 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 forwardlooking 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 SUBSIDIARY

Condensed Consolidated Balance Sheets (unaudited)

(in thousands)

		September 30, 2022		December 31, 2021	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	51,684	\$	2,178	
Prepaid expenses and other current assets		2,779		291	
Total current assets		54,463		2,469	
Property and equipment, net		1,250		1,173	
Right-of-use assets		1,050		1,611	
Deposits and other assets		259		200	
Total assets	\$	57,022	\$	5,453	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	1,969	\$	281	
Accrued expenses		1,853		895	
Accrued compensation expense		555		_	
Current operating lease liabilities		1,243		910	
Total current liabilities		5,620		2,086	
Long term operating lease liabilities		42		902	
Total liabilities		5,662		2,988	
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: 50,736 as of September 30, 2022 and 36,803 as of December 31, 2021		109,050		54,649	
Additional paid-in capital		7,838		6,713	
Accumulated other comprehensive loss		(26)		_	
Accumulated deficit		(65,502)		(58,897)	
Total stockholders' equity		51,360		2,465	
Total liabilities and stockholders' equity	\$	57,022	\$	5,453	

VIVANI MEDICAL, INC. AND SUBSIDIARY

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except per share data)

		Three Months Ended September 30,			Nine Months Ended September 30,			
	_	2022		2021		2022		2021
Operating expenses:								
Research and development, net of grants	\$	3,855	\$	2,868	\$	9,738	\$	8,027
Clinical and regulatory, net of grants		4		_		4		_
General and administrative		1,585		617		3,709		1,748
Total operating expenses		5,444		3,485		13,451		9,775
Loss from operations		(5,444)		(3,485)		(13,451)		(9,775)
Other income (expense), net	_	6,867		(6)	_	6,846	_	622
Net income/(loss)	\$	1,423	\$	(3,491)	\$	(6,605)	\$	(9,153)
Net income/(loss) per common share – basic	\$	0.04	\$	(0.10)	\$	(0.18)	\$	(0.28)
Net income/(loss) per common share – diluted	\$	0.04	\$	(0.10)	\$	(0.18)	\$	(0.28)
Weight all common about a state of the common and t		37,965		33,799		37,712		32,771
Weighted average common shares outstanding – basic	_	•	_		_		_	
Weighted average common shares outstanding – diluted	=	38,477		33,799	_	37,712	_	32,771

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