

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 14, 2022

VIVANI MEDICAL, INC.

(Exact name of registrant as specified in its charter)

**California**  
(State or other jurisdiction of  
incorporation)

**001-36747**  
(Commission  
File Number)

**02-0692322**  
(IRS Employer  
Identification No.)

**5858 Horton Street, Suite 280**  
**Emeryville, California**  
(Address of principal executive offices)

**94608**  
(Zip Code)

Registrant's telephone number, including area code: **(818) 833-5000**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	VANI	Nasdaq Capital Market
Warrants	VANIW	

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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## ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On November 14, 2022, Vivani Medical, Inc. (the “*Company*”) issued a press release announcing its financial and operating results for the three-months and nine-months ended September 30, 2022. A copy of the Company’s press release entitled “Vivani Medical Reports Third Quarter 2022 Results and Provides Business Updates” is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

## ITEM 7.01. REGULATION FD DISCLOSURE

On November 14, 2022, the Company issued the press release described above in Item 2.02 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item shall not be deemed “filed” for the purpose of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

## ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

Exhibit No.	Description
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<a href="#">99.1</a>	<a href="#">Press Release issued November 14, 2022 “Vivani Medical Reports Third Quarter 2022 Results and Provides Business Updates”</a>
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### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**VIVANI MEDICAL, INC.**

Date: November 14, 2022

By: /s/ Donald Dwyer  
Donald Dwyer  
Chief Business Officer

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## Vivani Medical Reports Third Quarter 2022 Results and Provides Business Updates

Emeryville, CA. -- (BUSINESS WIRE) -- Nov. 14, 2022 – 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 NPM-119. 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.”

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### **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.

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## **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, 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 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.

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**VIVANI MEDICAL, INC.  
AND SUBSIDIARY**

**Condensed Consolidated Balance Sheets (unaudited)**  
(in thousands)

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 51,684	\$ 2,178
Prepaid expenses and other current assets	2,779	291
<b>Total current assets</b>	<b>54,463</b>	<b>2,469</b>
Property and equipment, net	1,250	1,173
Right-of-use assets	1,050	1,611
Deposits and other assets	259	200
<b>Total assets</b>	<b>\$ 57,022</b>	<b>\$ 5,453</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,969	\$ 281
Accrued expenses	1,853	895
Accrued compensation expense	555	—
Current operating lease liabilities	1,243	910
<b>Total current liabilities</b>	<b>5,620</b>	<b>2,086</b>
Long term operating lease liabilities	42	902
<b>Total liabilities</b>	<b>5,662</b>	<b>2,988</b>
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)
<b>Total stockholders' equity</b>	<b>51,360</b>	<b>2,465</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 57,022</b>	<b>\$ 5,453</b>

**VIVANI MEDICAL, INC.  
AND SUBSIDIARY**

**Condensed Consolidated Statements of Operations (unaudited)**  
(in thousands, except per share data)

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
<b>Operating expenses:</b>				
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
<b>Total operating expenses</b>	<b>5,444</b>	<b>3,485</b>	<b>13,451</b>	<b>9,775</b>
Loss from operations	(5,444)	(3,485)	(13,451)	(9,775)
Other income (expense), net	6,867	(6)	6,846	622
<b>Net income/(loss)</b>	<b>\$ 1,423</b>	<b>\$ (3,491)</b>	<b>\$ (6,605)</b>	<b>\$ (9,153)</b>
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)
Weighted average common shares outstanding – basic	37,965	33,799	37,712	32,771
Weighted average common shares outstanding – diluted	38,477	33,799	37,712	32,771